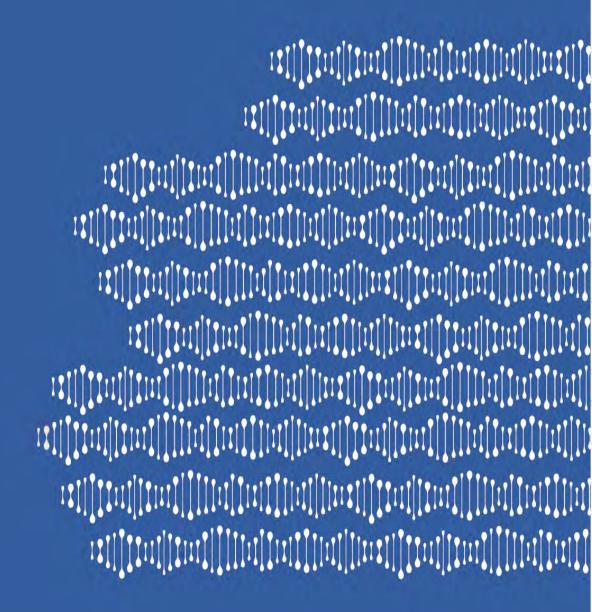
Oversight Committee Meeting

November 19, 2015





Summary Overview of the November 19, 2015, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the November 19, 2015, Oversight Committee meeting.

CEO Report

Wayne Roberts will present the CEO's report and address issues including the CPRIT 2015 Conference, staff recruitment efforts, grant amounts awarded for FY 2015, agency funds available for FY 2016 grant awards, and other issues as appropriate.

Chief Scientific Officer Report and Grant Award Recommendations

Dr. Margaret Kripke will provide an update on the Academic Research Program and present the Program Integration Committee's recommendations for 60 academic research awards, including 5_recruitment awards.

Information related to the Academic Research grant applications recommended for funding is not publicly disclosed until the Oversight Committee meeting. The information has been made available to board members through a secure electronic portal.

Chief Prevention and Communications Officer Report and Grant Award Recommendations

Dr. Becky Garcia will give a report regarding the Prevention Program activities and present the Program Integration Committee's recommendations for 12 prevention awards. Dr. Garcia will also provide an overview of the agency's communications activities including the CPRIT 2015 Conference, earned media, and the new CPRIT accomplishments brochure.

Information related to the prevention grant applications recommended for funding is not publicly disclosed until the Oversight Committee meeting. The information has been made available to board members through a secure electronic portal.

Chief Product Development Officer Report and Grant Award Recommendation

Michael Lang will provide a Product Development Research Program update and present the Program Integration Committee's recommendation for a company award.

Information related to the product development research grant application recommended for funding is not publicly disclosed until the Oversight Committee meeting. The information has been made available to board members through a secure electronic portal.

Scientific Research and Prevention Programs Committee Appointments

The Chief Executive Officer has appointed four new members to CPRIT's Scientific Research and Prevention Programs Committees. CPRIT's statute requires the appointments to be approved

by the Oversight Committee. A biographical sketch for each appointee is included in the board packet.

Internal Auditor Report

Weaver and Tidwell, CPRIT's internal auditor, will present a status report on CPRIT's outsourced internal audit services, several process-specific final internal audit reports, the internal audit risk assessment report, and CPRIT's FY 2015 annual internal audit report.

FY 2016 Program Priorities

Mr. Roberts will present the FY 2016 Program Priorities for approval. The Prevention, Scientific Research, and Product Development Research subcommittees reviewed the FY 2015 program priorities and determined that no changes to the priorities were needed for FY 2016.

Change to CPRIT's Bylaws

Kristen Doyle will present the proposed change to Section 6.3 of the Oversight Committee Bylaws for approval. The change clarifies contract delegation authority to the CEO and to the Chief Operating Officer when the CEO is unavailable.

Subcommittee Assignments

The Chair will present the proposed subcommittee assignments for FY 2016 – 2017 for approval by the Oversight Committee. A list of current subcommittees and proposed members is provided.

Changes to Agency Administrative Rules

Ms. Doyle will present proposed changes to the agency's administrative rules. Texas Health and Safety Code § 102.108 authorizes the Oversight Committee to implement rules to administer CPRIT's statute.

- Proposed rule changes to T.A.C. §§ 703.3, 703.11, 703.12, 703.13, 703.14, 703.20, and 703.21 are recommended to be published in the *Texas Register* for public input. A summary is provided for each of the proposed changes. These rule changes will be brought back to the Oversight Committee for final approval in February after the public has an opportunity to comment on the proposed rules.
- Rule changes to §§ 703.12 and 703.22 that were presented to the Oversight Committee in September are recommended for final adoption. The change to § 703.12 clarifies that cancer prevention grantees may spend some grant funds on indirect expenses, but are subject to the same limitation as cancer research grantees. New rule § 703.22 creates a compliance training requirement for new grantees and an annual compliance training component for all grantees with active CPRIT grants. Three comments were received from the public.

Advisory Committee on Childhood Cancer (ACCC) Charter amendment

Dr. Kripke will present proposed changes to the ACCC charter for Oversight Committee approval. The changes address committee membership, and terms for members and officers.

Chief Operating Officer Report

Heidi McConnell will present the operating budget, performance measures, and debt issuance history for the fourth quarter of FY 2015. She will also provide an overview of the FY 2016 activities, including CPRIT's ongoing annual independent financial audit.

Chief Compliance Officer Report

Vince Burgess will report on the status of required grantee reports, desk reviews and site visits as well as grantee training and technical assistance.



Oversight Committee Meeting Agenda

Texas State Capitol Extension 1400 N. Congress Avenue, Austin, Texas 78701 Room E1.012

> November 19, 2015 10:00 a.m.

The Oversight Committee may discuss or take action regarding any item on this agenda, and as authorized by the Texas Open Meetings Act, Texas Government Code Section 551.001 et seq., may meet in closed session concerning any and all purposes permitted by the Act.

1.	Call to Order	
2.	Roll Call/Excused Absences	
3.	Adoption of Minutes from the August 19, 2015, and September 10, 2015, meetings	TAB 1
4.	Public Comment*	
5.	Chief Executive Officer Report	TAB 2
	• FY 2015 Grant Awards Totals	
	• FY 2016 Proposed Budget - Grant Awards	
6.	Chief Scientific Officer Report	TAB 3
	Academic Research Program Report	
	Grant Award Recommendations	
7.	Chief Prevention and Communications Officer Report	TAB 4
	Prevention Program Report	
	Grant Award Recommendations	
	PP120029 Contract Extension	
8.	Chief Product Development Officer Report	TAB 5
	Product Development Research Program Report	
	Grant Award Recommendations	
9.	Scientific Research and Prevention Program Committee Appointments	TAB 6
10.	Internal Auditor Report	TAB 7
	Internal Audit Report over Grant Management	
	• Internal Audit Follow Up Procedures Report over Prior Year Governance and	
	Information Technology Findings	
	• Internal Audit Follow Up Procedures Report over Prior Year Grantee Monitoring	
	Audit Findings	
	Internal Audit Report over Expenditures	
	• FY2016-FY2018 Internal Audit Plans	
	• FY2015 Internal Audit Annual Report	
11.	FY 2016 Program Priorities	TAB 8
	Proposed Amendment to Oversight Committee Bylaws	TAB 9
13.	Subcommittee Assignments	TAB 10

14. Proposed Amendments to 25 T.A.C. Chapter 703 and Authorization to Publish	TAB 11
in Texas Register	
15. Final Order Approving Amendments to 25 T.A.C. Chapter 703	TAB 12
16. Advisory Committee on Childhood Cancer – Charter Amendment	TAB 13
17. Chief Operating Officer Report	TAB 14
18. Chief Compliance Officer Report	TAB 15
19. Chief Prevention and Communications Officer Report	TAB 16
Communications Report	
20. Personnel – Chief Scientific Officer	
21. Subcommittee Business	
22. Compliance Investigation Pursuant to Health & Safety Code § 102.2631	
23. Consultation with General Counsel	
24. Future Meeting Dates and Agenda Items	TAB 17
25. Adjourn	

^{*} Anyone wishing to make public comments must notify the Chief Executive Officer in writing prior to the start of the meeting. The Committee may limit the time a member of the public may speak.



Oversight Committee Meeting Minutes

August 19, 2015

1. Meeting Called to Order

A quorum being present, Dr. Rice, Chair, called the Oversight Committee to order at 10:01 a.m.

2. Roll Call /Excused Absences

Board Members Present:

Angelos Angelou

Donald (Dee) Margo

Pete Geren

Ned Holmes

Will Montgomery

Cynthia Mulrow, M.D.

Amy Mitchell (absent)

Bill Rice, M.D.

Craig Rosenfeld, M.D.

3. Oath of Office

Dr. Rice introduced the new member of the Oversight Committee, Mr. Donald (Dee) Margo. Mr. Margo was appointed by the Governor and confirmed by the Senate during the most recent legislative session.

Dr. Rice administered the oath of office to Mr. Margo.

4. Adoption of Minutes from the May 20 meeting (TAB 1)

MOTION:

Dr. Rice called for a motion to approve the minutes of the May 20, 2015, Oversight Committee meeting.

Motion made by Mr. Montgomery and seconded by Mr. Angelou.

MOTION CARRIED UNANIMOUSLY

5. Public Comment

Dr. Rice noted that no public comment requests had been received.

6. Chief Executive Officer Report (TAB 2)

Mr. Wayne Roberts, Chief Executive Officer, reported that applications had been received for both the Chief Product Development Officer (CPDO) and the Chief Scientific Officer (CSO). The period for submitting CPDO applications has closed. The interview committee (which includes Dr. Rice, Dr. Rosenfeld, Jack Geltosky, Chair of the Product Development Review Council, and CPRIT senior staff) will vet those applications.

A Bond Review Board meeting was held earlier this week where CPRIT's bond request was approved.

Mr. Roberts introduced a new staff member, Araceli Dwyer, Operations Specialist working with Lisa Nelson.

Mr. Roberts presented the chart "Summary of the Grant Awards Available", which is located in the meeting book. He explained that when the Program Integration Committee (PIC) met, it appeared that CPRIT would have more recruitment applications recommended for funding than funds available. However, one applicant has since withdrawn from consideration, leaving a sufficient balance for today's award recommendations.

There were no questions for Mr. Roberts.

7. Chief Scientific Officer Report (TAB 3)

Dr. Margaret Kripke, Chief Scientific Officer (CSO) gave the following Academic Research Program report:

Research Grants

- 480 applications have been received for the first cycle of FY 2016 (Individual Investigator and Targeted Individual Investigator awards) and are under review:
 - Targeted Awards: 45 applications for childhood cancer, 45 for prevention, and 50 for computational biology
 - Training Awards: both renewals and new applications have been received. This cycle, applications were accepted for a second award per institution if the application dealt with prevention or epidemiology. These applications will be peer reviewed in Dallas from September 29 to October 7, 2015.
- The second cycle of applications just opened and include the High Impact/High Risk and Multi-Investigator applications, and an opportunity to renew the Core

Facility awards that are expiring at the end of this year. CPRIT held a webinar to give more information about the Multi-Investigators awards and it is expected this will increase the number of applications received.

Recruitment Grants

Most recruitment applications are received between May and August, and this
cycle has been active.

Dr. Kripke stated that for the recruitment cycle to be considered today, 18 applications were reviewed with 10 recommended for grant awards by the Scientific Review Council (SRC), which is a 56% success rate. Of the 10 that were recommended for grants, seven have informally committed that they will accept an award if one is extended. That would make CPRIT's success rate in recruiting applications for whom offers will be made about 70%, a percentage that has been consistent throughout the history of these awards.

The total for PIC recruitment recommendations today is \$23 million dollars.

Historical Recruitment Statistics by FY, Quarter, Number, and Award Amount

Dr. Kripke gave a historical summary of recruitment statistics, which can be found behind Tab 3 of the meeting materials. The table shows that the majority of awards are made in the 4th quarter of the fiscal year.

Five recruitment applications are expected to be recommended by the SRC for the Oversight Committee's approval in September totaling approximately \$20 million. The total for all recruitment applications received for FY 2015 is \$70 million but some will be forwarded into next year for funding. Dr. Kripke said that, regarding recruitment awards, it is probably time to decide: whether the number of these awards should be limited; whether funds should be reserved for the end of the fiscal year when most of the applications are received to ensure funding is available; and how much money should be spent on this award mechanism.

University Advisory Committee

The committee will meet August 21, 2015, and a report will be given at the September Oversight Committee meeting.

Responding to a question about how many recruitment awardees stay beyond a 2-3 year period. Dr. Kripke explained that the Established Investigator recruitment awards are for five year terms. The first ones awarded in 2010 are just now reaching the end of the five-year grant award period, so it is a little early to tell. However, to her knowledge, none of those awardees have left. One Rising Star awardee is leaving for personal reasons, but that is the only one to date.

An Oversight Committee member asked Dr. Kripke what her opinion is on whether CPRIT was allocating enough money to the recruitment program. Dr. Kripke said currently enough funds have been allocated to cover all approved applications. The PIC has not denied any award based on financial considerations. This year, though, some of the awards were held for the next budget year (FY16) due to a lack of funds, so a point could be coming where a decision must be made on whether this is CPRIT's top priority program. Also, a discussion should occur on whether CPRIT should recruit as many people as are approved, or limit either the number of people or the number of dollars and leave funds for other programs. This decision will need to be made at the Oversight Committee level.

Dr. Rice noted that the money allocated to recruitment awards is spent on cancer research.

An Oversight Committee member asked if there were any general principles that should be applied to the approval of the number of, for example, First Time Investigators versus Established Investigators. More First Time Investigators could be recruited for a set amount of funds than Established Investigators, since the latter require three time the funding. Dr. Kripke responded that CPRIT has no control over the number of applications submitted for each mechanism. However, established investigators are harder to recruit as they are already established somewhere else, but when they do come they bring grant money and staff with them, enriching the program.

An Oversight Committee member pointed out that one of the major components of curing cancer is intellectual property, and asked whether CPRIT staff knew how many patents have been issued to investigators and/or researchers receiving CPRIT funding, Dr. Kripke stated that CPRIT may have that information, but staff would need to compile it. Further, she stated the number of patents would not be a good measure of success by itself because many patents do not result in an actual viable product. She also noted that since High Impact/High Risk grants are two-year awards, enough have now been awarded that those awards could be analyzed to measure their success. Dr. Kripke feels that grantees would be more forth-coming with this kind of information if outside consultants asked the questions instead of CPRIT staff.

In response to a question regarding measuring success, Dr. Kripke stated that information on the number of companies that have resulted from CPRIT funding is collected in the grantee annual progress reports and final progress reports at the end of the grant. These reports also contain information on whether CPRIT funding led to follow-on funding. However, once the grant is over, the reporting stops. Many times it is a year or two before the work leads to follow-on funding or a company formation. Therefore, Dr. Kripke did not think it is accurate to only use the data grantees report to measure success. Instead, additional interviewing of grantees by consultants would be beneficial.

Mr. Roberts noted here that CPRIT staff have begun developing a project where all principal investigators of closed grants are interviewed to learn what the grantees discovered and what relevance their discoveries have for cancer research. Staff has had some discussions with The University of Texas System regarding participating with CPRIT in this project.

An Oversight Committee member asked Dr. Kripke whether the applications in computational biology are coming from all over the state or from a particular institution. Dr. Kripke stated she did not have that information available, but computational biology applications will come from institutions with enough faculty in that area to be able to apply.

Grant Award Recommendations

Dr. Kripke noted changes to the award recommendations provided behind Tab 3 of the Oversight Committee meeting materials. The two First Time, Tenure-Track Faculty applicants (RR150071 and RR150075) withdrew after favorable reports from the SRC but before consideration by the PIC. Dr. Kripke noted that both of these candidates were given the highest possible score by the SRC, which illustrates how highly sought-after these candidates are. Dr. Kripke noted that another First Time, Tenure-Track Faculty applicant (RR150082) withdrew from consideration after approval by the PIC.

Dr. Kripke stated:

- 7 candidates were being presented for Oversight Committee consideration (56% of the applicants reviewed).
- 2 were Established Investigators
- 5 were First-time, Tenure-Track Faculty Members
- Information on the candidates was in the Oversight Committee meeting materials, Tab 3.

There were no further questions for Dr. Kripke.

Research Grant Award Recommendations

App ID	Mech.	Organization/Company	Candidate	Budget Requested
RR150074	RFT	The University of Texas Southwestern Medical Center	Dr. Jan Erzberger	\$2,000,000
RR150076	RFT	The University of Texas Southwestern Medical Center	Dr. Kendra King Frederick	\$3,000,000
RR150072	REI	The University of Texas Southwestern Medical Center	Dr. Yang-Xin Fu	\$6,000,000

App ID	Mech.	Organization/Company	Candidate	Budget Requested
RR150093	RFT	Baylor College of Medicine	Dr. Charles Y. Lin	\$2,000,000
RR150085	RFT	The University of Texas Health Science Center at Houston	Dr. Leng Han	\$2,000,000
RR150088	REI	University of Houston	Dr. Frank McKeon	\$6,000,000
RR150089	RFT	The University of Texas Southwestern Medical Center	Dr. Peter M. Douglas	\$2,000,000

RFT = Recruitment of First-Time, Tenure-Track Faculty Members REI = Recruitment of Established Investigators

NOTE: RR150071 and RR150075 were withdrawn by the applicants after the SRC meeting but before the PIC meeting. RR150082 withdrew after the PIC meeting but before the Oversight Committee meeting.

COMPLIANCE CERTIFICATION

Mr. Vince Burgess, Chief Compliance Officer, presented his report on the Academic Research Program Awards review process and certified the recommended awards for Oversight Committee approval.

Dr. Rice noted that the pedigree for each application was located in the meeting materials.

CONFLICT OF INTEREST NOTIFICATIONS

Dr. Rice stated for the record that the only Oversight Committee member to have reported conflicts of interest with the applications to be considered was unable to attend this meeting.

No other conflicts were reported.

MOTION:

Dr. Rice called for a motion to approve each of the PIC's recommendations for Recruitment of Established Investigators and First-Time, Tenure-Track Faculty, noting for the record that RR150071, RR850075, and RR150082 have withdrawn their applications.

Motion made by Mr. Geren and seconded by Mr. Montgomery.

MOTION CARRIED UNANIMOUSLY

MOTION:

Dr. Rice called for a motion delegating contract negotiation authority to the Chief Executive Officer and the General Counsel and to authorize the Chief Executive Officer to sign the contracts on behalf of CPRIT.

Motion made by Mr. Montgomery and seconded by Mr. Angelou.

MOTION CARRIED UNANIMOUSLY

Dr. Rice stated that the Interim Chief Product Development Officer Report (TAB 4) would be taken up later in the meeting.

8. Scientific Research and Prevention Program Committee Appointments (TAB 5)

Mr. Roberts stated that in the meeting materials was a memo from Mr. Holmes, Chair of the Nominations Subcommittee, recommending approval of the Chief Executive Officer's appointments to the Scientific Research and Prevention Program Committees: three to the Prevention Program review panels and nine to the Academic Research Program review panels.

MOTION:

Dr. Rice called for a motion to approve the Scientific Research and Prevention Program Committee appointments.

Motion made by Mr. Holmes and seconded by Mr. Margo.

MOTION CARRIED UNANIMOUSLY

9. FY 2016 Honoraria Policy (TAB 6)

Mr. Roberts stated that the CEO is required to annually update the honoraria policy, with input from the Oversight Committee. The honoraria policy addresses the amounts paid to approximately 240 peer reviewers. The recommended FY 2016 policy, exactly the same as the FY 2015 policy, is in the meeting materials.

MOTION:

Dr. Rice called for a motion to approve the proposed honoraria policy for FY 2016.

Motion made by Mr. Geren and seconded by Mr. Margo.

MOTION CARRIED UNANIMOUSLY

10. Health & Safety Code Section 102.1062 Waivers (TAB 7)

Mr. Roberts explained that the statute provides a process for individuals with conflicts of interest to participate in various aspects of CPRIT's review and approval process. Texas Health and Safety Code 102.1062 allows for the waiver of conflict of interest requirements under exceptional circumstances, upon approval by the Oversight

Committee. Mr. Roberts presented his recommendations for FY 2016 waivers for the following individuals:

- Dr. Margaret Kripke: Dr. Kripke's waiver is proposed because her husband is an employee of MD Anderson Cancer Center, which is a CPRIT grantee and grant applicant. The waiver is the same as the one that was approved for FY 2015.
- Mr. Kirk Cole, Commissioner of the Department of State Health Services: Mr. Cole is a statutorily required member of the PIC. The DSHS is a prevention grantee and a potential applicant. This is the same waiver approved previously.
- Mr. Will Montgomery: Mr. Montgomery is a partner at Jackson Walker LLP. The firm represents various entities that are either grant applicants or grantees; however, Mr. Montgomery does not personally represent any CPRIT applicants or grantees. This is the essentially the same waiver previously approved for Mr. Montgomery in FY 2015, with the addition of six more entities..
- Mr. Donald Brandy: Mr. Brandy is the CPRIT purchaser who referees tennis matches at The University of Texas and other universities in the area, for which he receives payment from the athletic department. This outside employment does not affect his work at CPRIT. The Oversight Committee approved the same waiver for FY 2015.
- Ms. Amy Mitchell: A waiver for Ms. Mitchell is being requested because she is senior counsel at Norton Rose Fulbright, which represents various grant applicants and grantees.

MOTION:

Dr. Rice called for a motion to approve proposed Health & Safety Code Section 102.1062 waivers.

Motion made by Dr. Rosenfeld and seconded by Mr. Geren.

MOTION CARRIED UNANIMOUSLY

11. Final Order Approving Amendments to 25 T.A.C. Chapter 703 (TAB 8)

Ms. Cameron Eckel, Staff Attorney, presented the proposed rule change to 25 T.A.C. Chapter 703. She stated the proposed amendment was provisionally approved by the Oversight Committee at the May 2015 meeting and was published in the *Texas Register* for comments. No public comments were received. The proposed changes outline the deferral process for grant applications for both the PIC and Oversight Committee. The rules were published in the *Texas Register* on June 5, 2015.

Dr. Rice referred to a memo in the meeting materials from the Board Governance Subcommittee Chair recommending approval of these rule changes.

MOTION:

Dr. Rice entertained a motion to approve the final order adopting CPRIT's rule change and to direct staff to file the orders with the Secretary of State.

Motion was made by Mr. Geren and seconded by Mr. Montgomery.

MOTION CARRIED UNANIMOUSLY

12. Report Regarding Texas Ethics Commission Advisory Opinion (TAB 9)

Mr. Roberts referred to a briefing memo in the meeting book from Kristen Doyle, General Counsel, and Cameron Eckel, Staff Attorney. The Texas Ethics Commission (TEC) Advisory Opinion No. 530, issued August 7, 2015, determined that, based on changes to CPRIT's enabling legislation in the 2013 legislative session, CPRIT Oversight Committee members are not considered "state officers" for the purposes of Texas Government Code Chapter 572. For this reason, the standards of conduct and conflicts of interest set out in that code do not apply to Oversight Committee members. However, requirements contained in CPRIT's statute, administrative rules, and code of conduct, include many of the requirements that are contained in Chapter 572. CPRIT's Board Governance Subcommittee met August 6, 2015, and directed legal staff to draft a resolution stating the Oversight Committee's intent to abide by the transparency and accountability provisions of Chapter 572.

Dr. Rice noted that the wording in the resolution related to personal financial statements stating "may file" should be changed to "will file" since this will most likely be required when the issue is addressed in the next session.

An Oversight Committee member asked if this TEC determination was unique to CPRIT. Mr. Roberts responded that it was due to the wording of CPRIT's enabling legislation stating that committee members serve "at the will" of the appointing officers as opposed to a specific term.

MOTION:

Dr. Rice entertained a motion to approve adoption of a resolution affirming the CPRIT Oversight Committee's commitment to accountability and transparency, with the wording change from "may" to "will."

Motion was made by Mr. Geren and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

13. Contract Approvals (TAB 10)

Ms. Heidi McConnell, Chief Operating Officer, reported on six contracts totaling approximately \$1.5 million requiring Oversight Committee approval. All are renewals except for the Perryman Group contract. The Compliance Monitoring and Due Diligence

contracts will also have to be approved by the Legislative Budget Board before CPRIT can execute the contracts. The other five contracts will be executed by CPRIT upon Oversight Committee approval.

- Compliance Monitoring Support Services (CohnReznick)
- Due Diligence Services (ICON Clinical Research)
- Economic Assessment of Cost of Cancer in Texas (The Perryman Group)
- Outside Legal Services (Vinson & Elkins)
- Outside Legal Services (Yudell Isidore)
- Strategic Communication Program Services (Hahn Public Communications)

Dr. Rice stated the Audit Subcommittee had reviewed the contracts and recommended approval.

Dr. Rice noted no conflicts were reported.

MOTION:

Dr. Rice entertained a motion to approve service contracts for CohnReznick, ICON Clinical Research, The Perryman Group, Vinson & Elkins, Yudell Isidore, and Hahn Public Communications.

Motion was made by Mr. Montgomery and seconded by Mr. Geren,

MOTION CARRIED UNANIMOUSLY

14. Chief Prevention and Communications Officer Report (TAB 11)

Dr. Rebecca Garcia presented the Prevention Program Report:

<u>FY2016 Review Cycle 1</u>: Twenty applications have been received for the 5 RFAs released in this cycle. Peer Review will take place in September and recommendations will be presented to the Oversight Committee in November.

<u>FY2016 Review Cycle 2</u>: RFAs will be released in September. A new RFA is the result of collaboration between CPRIT and the College of American Pathologists (CAP) Foundation for a one-day community-based cervical and breast cancer screening program organized by pathologists in partnership with medical facilities. The program is unique in that it provides same-day results, some follow-up care on the day of the program, and a plan of action for further treatment if required.

Other Activities:

Dr. Garcia reported that staff has been visiting areas of the state where there are few CPRIT prevention grants and scheduling meetings with health care providers and community organizations to discuss community needs, barriers to applying for CPRIT awards, and current funding opportunities.

In response to a question about collecting county impact data, Dr. Garcia said CPRIT had surveyed grantees to see whether they already collect that information or if they can collect it easily. As a result of the survey, CPRIT will begin asking grantees to collect county impact data. Grantees will be given one quarter to get their reporting systems in place and then they will begin reporting quarterly. However, the information will be reported manually, outside of our electronic system until changes can be made to CPRIT's grants management system.

Communications Report

<u>CPRIT Conference</u>: The call for abstracts closed August 14, 2015. CPRIT has received 528 abstract submissions (in 2012 there were 423 presented). The abstracts are currently being reviewed. The breakdown on numbers of abstracts by categories will be available soon. It is expected that we will accept and can accommodate the majority of abstracts submitted. Abstracts will be presented as posters during two poster sessions. In addition, Dr. Kripke will select 5-6 abstracts to be presented in oral sessions.

As of August 18, 192 people had registered for the conference, but it is expected that those who submitted abstracts are waiting to receive notification of acceptance before registering.

In response to questions about promotion of the conference, Mr. Roberts stated he will be sending targeted invitations to state legislators and leadership. CPRIT was also asked to consider sending special invitations to the presidents of universities and chairmen of the cancer centers. Dr. Garcia reports that the press will also be invited to the conference.

Opportunities for networking at the conference include the poster sessions, the lunch hour, and a Prevention networking session that grantees requested. Product Development is considering designating time for networking. There is a networking meeting planned for those interested and working on colorectal cancer screening. The Advisory Committee on Childhood Cancer will also hold a meeting at the conference.

Other Communications Activities

Dr. Garcia said a press release announcing that Prevention grantees surpassed the \$2 million mark in prevention services delivered is being prepared.

15. Internal Auditor Report (TAB 12)

Alyssa Martin of Weaver and Tidwell, LLP (Weaver), CPRIT's internal audit services contractor for fiscal year 2015, presented the internal auditor report. She gave an overview of the updated FY 2015 Internal Audit Plan and Status, which can be found in the meeting materials.

Ms. Martin stated there were five items on the previously approved audit plan:

- Grants Management
- Expenditures
- Information Technology
- Grantee Field Audits
- Special Projects

Since the Compliance division now audits grantees regularly, Ms. Martin stated it was not necessary for the internal auditors to spend extensive time in that area. Therefore, the audit plan was revised as follows:

- Risk Assessment
- Grants Management
- Expenditures
- Follow-up Procedures Over Prior Year Information Technology and Governance Findings
- Follow-up Procedures Over Prior Year Grantee Field Audit Findings
- Project Management and Annual Report
- Special Projects

In response to an Oversight Committee member question, Ms. Martin stated all projects will be completed in August and the report will be completed during the month of September. A draft report will provided to CPRIT management and management's response will be included in the final report.

An Oversight Committee member asked for a further explanation of what the Risk Assessment entailed and what time period was evaluated. Ms. Martin responded that the Risk Assessment was a forward-looking, point-in-time assessment of the relevant risk categories of the business and organizational processes that CPRIT has to execute against. It is done for the purpose of building an internal audit plan. Weaver reviewed the risk assessment performed by the prior internal auditors over the last two years and updated the methodology for internal audit purposes. Weaver is in the process of performing that risk assessment and a risk rating meeting with management will be held in the coming week.

Mr. Roberts stated the Audit Subcommittee will review the final report before it is presented to the full Oversight Committee.

16. Interim Chief Product Development Officer Report (TAB 4)

Mr. Roberts stated that the Product Development report would be delayed until the September meeting when Ms. Kristen Doyle, General Counsel and Interim Chief Product Development Office, could present the report in detail.

Consultation with General Counsel (taken out of order)

Dr. Rice stated that CPRIT's legal counsel is negotiating revenue sharing terms to be included in a Product Development contract and the Oversight Committee thus needs to seek legal advice, pursuant to Texas Open Meetings Act Section 551.071. Dr. Rice called the meeting into executive session, including Wayne Roberts, CEO, and Cameron Eckel, legal counsel. In addition, CPRIT's outside counsel, Carmelo Gordian and Michelle Kwan, joined the executive session.

Dr. Rice convened the closed session at 11:29 a.m.

Dr. Rice reconvened the open meeting at 12:30 p.m.

Dr. Rice stated for the record that the following motion results from unique circumstances and does not constitute a precedence for any other equity decisions.

MOTION:

Dr. Rice entertained a motion to authorize the Chief Executive Officer to negotiate and to execute a contract, pursuant to the terms and changes discussed during the executive session, with the advice of both outside counsel and CPRIT's legal counsel.

Motion was made by Mr. Angelou and seconded by Dr. Rosenfeld. Dr. Mulrow opposed.

MOTION CARRIED

MOTION:

Dr. Rice entertained a motion to direct the Chief Executive Officer to develop policies and procedures for the Oversight Committee's use in future equity agreements, the policies and procedures to be presented to the Oversight Committee at a future meeting.

Motion was made by Mr. Holmes and seconded by Dr. Rosenfeld.

MOTION CARRIED UNANIMOUSLY

17. Chief Compliance Officer Report (TAB 13)

Mr. Vince Burgess, Chief Compliance Officer, reported on compliance activities:

- Submission Status of Required Grant Recipient Reports
- CPRIT's Grant Reports Reconciliation Project
 - o 65 reports by 16 entities were still outstanding
- Compliance Program Activities
 - o Training session provided to grantees
 - o FSR reviews
 - o Desk reviews
 - On-site visits
 - Compliance Reporting

- Risk Assessment Model for determining grantee risk and need for review
 - Financial exposure
 - o Entity maturity
 - o Prior experience administering grants
- Fraud, Waste, and Abuse Hotline
 - CPRIT implemented a compliance and ethics hotline on July 1, 2015, called "Red Flag Reporting" which is a service that allows individuals to report anonymously.

An Oversight Committee member asked if the outstanding grantee reports could be categorized by importance. Mr. Burgess stated a number of reports are matching certifications, interim reports, and some revenue sharing progress reports—an even spread of reports.

18. Chief Operating Officer Report (TAB 14)

Ms. Heidi McConnell, Chief Operating Officer, presented the Chief Operating Officer Report, which covered:

- CPRIT Financial Overview for FY 2015, Quarter 3
 - o FY 2015, 3rd Quarter Operating Budget
 - o FY 2015 3rd Quarter Performance Measures
 - o Debt Issuance Report

An Oversight Committee member asked if it matters whether CPRIT issues commercial notes or bonds. Ms. McConnell stated it doesn't, but commercial notes are quicker to prepare for than bonds.

FY 2016 Budget Overview

Wayne noted that even with additional staff being hired, our calculated administrative costs is under 6%.

19. FY 2016 Program Priorities Process (TAB 15)

Mr. Roberts reported that each program subcommittee had met and decided that CPRIT should continue the program priorities adopted in November 2014, largely on the basis that CPRIT is just beginning to issue RFAs based on those priorities. A final decision will be brought to the Oversight Committee for consideration in November.

20. Personnel – Chief Scientific Officer, Chief Product Development Officer

Mr. Roberts stated he had covered this issue during his CEO report and had no additional comments. Oversight Committee members did not have comments or questions.

21. Subcommittee Assignments (TAB 16)

Mr. Roberts suggested taking this item up at the September meeting as three members had to leave today's meeting early. Dr. Rice stated the members could look over the current subcommittee assignments and further discussion will be taken up at the September meeting. Oversight Committee members did not have comments or questions.

22. Subcommittee Business

Dr. Rice stated there was no subcommittee business to be taken up.

23. Officer Elections (TAB 17)

Mr. Ned Holmes, Chair of the Nominations Subcommittee, presented the subcommittee's unanimous recommendation for the following slate of officers: Pete Geren as presiding officer; Will Montgomery as assistant presiding officer; and Amy Mitchell as secretary.

MOTION:

Dr. Rice entertained a motion to approve the recommended slate of officers: Pete Geren as presiding officer, Will Montgomery as assistant presiding officer, and Amy Mitchell as secretary.

Motion was made by Mr. Angelou and seconded by Dr. Mulrow.

MOTION CARRIED UNANIMOUSLY

24. Compliance Investigation Pursuant to Health & Safety Code § 102.2631

Dr. Rice stated this item will be taken up at the next meeting.

25. Consultation with General Counsel

This item was taken out of order.

MOTION:

Dr. Rice entertained a motion to excuse the absence of Ms. Amy Mitchell.

Motion was made by Mr. Holmes and seconded by Mr. Montgomery.

MOTION CARRIED UNANIMOUSLY

26. Future Meeting Dates and Agenda Items (TAB 18)

Dr. Rice noted the next Oversight Committee meeting is scheduled for September 10, 2015, starting at 1:00 p.m. CPRIT staff will circulate a tentative agenda prior to the meeting. The meeting packet includes calendars for FY 2016 and FY 2017 outlining the Oversight Committee and subcommittee schedule.

Mr. Geren requested that the November meeting be moved to the 19th. Discussion will take place at the September meeting.

RESOLUTION:

Mr. Montgomery proposed a resolution honoring Dr. Rice for his service as presiding officer.

MOTION:

Mr. Montgomery called for a motion to approve the proposed resolution honoring Dr. Rice for his service as presiding officer.

Motion was made by Dr. Rosenfeld and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

27. Adjourn

There 1	being no	further	business,	Dr.	Rice ad	iourned	the	meeting	at 2:55	p.m

	_	
Signature		Date



Oversight Committee Meeting Minutes

September 10, 2015

1. Meeting Called to Order

A quorum being present, Mr. Geren, presiding officer, called the Oversight Committee to order at 12:01 p.m.

2. Roll Call /Excused Absences

Board Members Present:

Angelos Angelou Donald (Dee) Margo Pete Geren Ned Holmes Will Montgomery Cynthia Mulrow, M.D. Amy Mitchell Bill Rice, M.D. (absent) Craig Rosenfeld, M.D.

MOTION:

Mr. Geren called for a motion to excuse the absence of Dr. Rice.

Motion made by Mr. Holmes and seconded by Dr. Rosenfeld.

MOTION CARRIED UNANIMOUSLY

3. Public Comment

Mr. Geren noted that no public comment requests had been received.

4. Chief Executive Officer Report (TAB 1)

Mr. Wayne Roberts, Chief Executive Officer, reported on upcoming activities:

Travel Activities:

On September 16-17, Mr. Roberts will be attending the Sixth Annual Childhood Cancer Summit in Washington, D.C., co-chaired by Congressman Michael McCall and Congressman Chris Van Hollen. While in Washington, D.C., he'll visit the offices of SRA International, CPRIT's third-party grants administrator.

Personnel

Since the August meeting, two grant accountants have been hired. Both the Chief Scientific Officer and the Chief Product Development Officer recruitment searches are entering the interview phase.

Program Activities

The three programs, Academic Research, Product Development Research, and Prevention, will be having peer review and review council meetings.

CPRIT Biennial Conference

The biennial conference will be in Austin on November 9 and 10, 2015. It appears at this time there will approximately 800 attendees.

Other Activities:

- Preparation of the legislatively required Annual Report has begun. It is due in January but most of the work should be completed by the end of December.
- Available funds for FY 2016 grant awards total \$286.9 million.

There were no questions for Mr. Roberts.

5. Chief Scientific Officer Report

Dr. Margaret Kripke, Chief Scientific Officer presented the grant award recommendations, which were in the meeting materials handout titled "Proposed Grant Awards."

Grant Recommendations:

- 12 applications were received in the last two cycles:
 - o 11 applications were reviewed.
 - o 1 application was administratively rejected.
 - o 5 were recommended:
 - 1 withdrew following the Program Integration Committee (PIC) meeting.
 - 4 are being recommended today for a total of \$15,700,000.

An Oversight Committee member asked if the applicant who withdrew gave a reason and Dr. Kripke responded that applicant took another position but it's not known where.

Re-nomination of Grant Application:

Dr. Kripke presented an application for funding of a First-time, Tenure-Track Recruitment Award for Dr. Peter Douglas. She stated that his recruitment grant was originally approved at the August 19, 2015. Following the meeting, CPRIT staff learned that Dr. Douglas had accepted a position at The University of Texas Southwestern Medical Center (UTSWMC) following the SRC's recommendation to approve a recruitment award, but prior to the grant being approved by the Oversight Committee.

The recruitment RFA states that applicants that are already employed by the institution are ineligible for a First-time, Tenure-Track award. However, the Scientific Review Council (SRC) felt his application worthy of funding and re-recommended it to the PIC in light of extenuating circumstances. The PIC recommended the award for Dr. Douglas in the amount of \$2 million (the original award amount), based on special circumstances.

Research Grant Award Recommendations

App ID	Mech.	Organization/Company	Candidate	Budget Requested
RR160009	RRS	Baylor College of Medicine	Chonghui Cheng	\$4,000,000
RR150104	RRS	The University of Texas Health Science Center at Houston	Dr. Wa Xian	\$3,700,000
RR150106	RFT	Baylor College of Medicine	Dr. Ronald Parchem	\$2,000,000
RR160005	REI	The University of Texas at Austin	Thomas Yankeelov	\$6,000,000

RFT = Recruitment of First-Time, Tenure-Track Faculty Members

REI = Recruitment of Established Investigators

RRS = Recruitment of Rising Stars

Note: RR150103 was withdrawn by the applicant after the PIC meeting.

COMPLIANCE CERTIFICATION

Mr. Vince Burgess, Chief Compliance Officer, presented his report on the Academic Research Program Awards review process and certified the recommended recruitment awards for Oversight Committee approval. He noted two compliance issues:

- The RFAs were not published in the *Texas Register*, as required by CPRIT's Administrative Code § 703.3, though they were published on CPRIT's website. The two applications impacted are RR160009 and RR160005.
- The recruitment grant RR150089, Dr. Peter Douglas, was approved at the August 2015 Oversight Committee meeting. CPRIT became aware after the meeting that Dr. Douglas had accepted a position at UTSWMC prior to that meeting. As the RFA prohibits employment at the recruiting institution prior to the grant award, the grant award was rescinded. The SRC met on September 1, 2015, to re-recommend this candidate, whom they felt worthy of the award, given the special circumstances.

An Oversight Committee member asked if failure to publish in the *Texas Register* prevented the committee from approving the grants and Mr. Burgess stated it did not. Ms. Doyle, General Counsel, stated that CPRIT's administrative rules require the RFAs are to be published in the *Texas Register* but the statute is silent on the issue. So, while CPRIT failed to comply with our process, it is not a statutory requirement.

Mr. Geren asked Mr. Roberts to address the compliance issues. Mr. Roberts stated although these issues were serious, he recommended the three awards affected by the compliance issues be approved due to extenuating circumstances:

- With regard to Mr. Douglas, UTSWMC had been notified of the SRC's intent to recommend his application to the Oversight Committee, as is CPRIT's normal procedure to ensure recruitment efforts are kept on track at the institutions. Due to family issues, UTSWMC allowed Mr. Douglas to arrive one month early. Based on this extenuating circumstance, he recommends the Oversight Committee approve the PIC's recommendation to award a First-time, Tenure Track recruitment grant to UTSWMC for the recruitment of Dr. Douglas, despite UTSWMC's failure to comply with the RFA.
 - O Going forward, the Chief Scientific Officer will revise the RFA and notification process to avoid this situation arising again. The Chief Compliance Officer will add a line to the Compliance Pedigree (examples in the meeting materials) for all recruitment grants to report whether offers have been made.
- With regard to applications RR16005 and RR16009, which were not published in the *Texas Register* in compliance with CPRIT's administrative rules, Mr. Roberts finds that the problem was caused by CPRIT and not as a result of any action by the institution or the applicants. The RFAs were available on CPRIT's public website since June 22, 2015. Further, there is no evidence that any application has been made as a result of the RFA being published in the *Texas Register*; the public is following our website and our list serve for announcements of RFAs. Therefore, it was determined that no one was disadvantaged as a result of the RFA not being published in the *Texas Register*. Based on the extenuating circumstance that the applicant had no way of addressing CPRIT's failure to follow process, Mr. Roberts finds that good cause exists to recommend approval of these two grants.

Mr. Geren noted for the record that CPRIT's Administrative Code specifically permits the Chief Executive Officer to recommend corrective actions to address compliance process issues.

In response to an Oversight Committee member question, Mr. Roberts and Mr. Burgess both affirmed that the applications at issue had been through the proper review process.

CONFLICT OF INTEREST NOTIFICATIONS

Mr. Geren stated for the record that no Oversight Committee member reported a conflict of interest with any application to be considered today.

No other conflicts were reported.

Mr. Geren noted for the record that RR150103 was withdrawn by the applicant after the PIC meeting.

MOTION:

Mr. Geren entertained a motion to approve the re-recommendation of RR150089 and the Chief Executive Officer's recommendation regarding extenuating circumstances.

Motion made by Mr. Montgomery and seconded by Dr. Mulrow. Dr. Rosenfeld opposed.

MOTION CARRIED

MOTION:

Mr. Geren entertained a motion to approve each of the Program Integration Committee's recommendations for Recruitment of Established Investigators, Recruitment of Rising Stars, and First-Time, Tenure-Track Faculty, and to approve the Chief Executive Officer's recommendation regarding extenuating circumstances related to RR160005 and RR160009.

Motion made by Mr. Montgomery and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

MOTION:

Mr. Geren entertained a motion delegating contract negotiation authority to the Chief Executive Officer and the General Counsel and to authorize the Chief Executive Officer to sign the contracts on behalf of CPRIT.

Motion made by Mr. Montgomery and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

6. Interim Product Development Officer Report (TAB 2)

Ms. Kristen Doyle, General Counsel and Interim Product Development Officer, reported on the Product Development program.

Current Program Update:

• CPRIT is accepting applications for Product Development awards through September 16, 2015.

• Due diligence is in progress on three applications that have made it through the review process. Any recommendations that come out of that due diligence process will be presented at the November Oversight Committee meeting.

Contract Extension - CP120036

Ms. Doyle reported that in March 2012 the Oversight Committee approved a \$15.6 million award to Cell Medica. The company requests an extension of that award so they will have time to complete work on the grant project. Had Cell Medica followed CPRIT's established process for requesting a no-cost extension, the request would have received routine approval because the project was up-to-date fiscally and making appropriate progress as judged by CPRIT's expert reviewers. However, Cell Medica was not advised of the extension request process and timeline when it sought advice from its primary CPRIT staff contacts, only assurances that the remaining funds could be carried forward into a fourth budget year.

Recommendation: Since CPRIT staff do not have authority to approve an extension when the request is received after the grant's termination date, Ms. Doyle recommends the Oversight Committee authorize Mr. Roberts to approve a no-cost extension for the Cell Medica contract that changes the termination date of the contract to May 31, 2016, allowing the company time to complete the work of the grant project and use remaining funding.

Ms. Doyle stated CPRIT staff will develop a process allowing the Chief Executive Officer to handle requests for contract extension which are not requested timely and bring an administrative rule to the Oversight Committee for approval.

There were no questions for Ms. Doyle regarding the contract extension.

MOTION:

Mr. Geren entertained a motion to approve a contract extension for CP120036 through May 31, 2016.

Motion made by Mr. Montgomery and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

7. Proposed Amendments to 25 T.A.C. Chapter 703 (TAB 3)

Ms. Doyle stated that Academic Research and Product Development Research grantees are allowed to spend up to 5% of grant funds on indirect costs, consistent with the statutory restriction on indirect costs paid for with cancer research funds. However, both the statute and CPRIT's administrative rules are silent with regard to allowable indirect costs for prevention grants, resulting in the Prevention Program currently prohibiting prevention grantees from expending any grant funds on indirect expenses. Ms. Doyle presented a proposed rule change to 25 T.A.C. Chapter 703.12 that allows prevention grantees to expend up to 5% of the grant funds on indirect costs.

Additionally, Ms. Doyle presented a proposed a new rule, 25 T.A.C. Chapter 703.22, that implements the internal auditor's recommendation that CPRIT establish a mandatory compliance onboarding program for new grantees as well as periodic compliance training for all grantees. The proposed rule directs the Chief Compliance Officer to create a training program to be required of grant recipients which addresses applicable financial, administrative, and program requirements related to proper stewardship over grant award funds, including grant reporting.

In response to an Oversight Committee member question, Ms. Doyle stated that the training will be required of the person authorized to sign on behalf of the institution (the individual responsible for signing off on any reports submitted) and at least one other employee at the grantee institution. Since grants are given to the institution, not individuals, the training is done by the authorized person for all the grants awarded to that particular institution.

A question was asked by an Oversight Committee member whether there will be options for smaller institutions that may not have the staff or funds to come to Austin for training. Ms. Doyle said that to accommodate everyone there will be recorded webinars, live webinars, and some on-site visits, so travel to Austin is not necessary to comply with the new requirement.

Mr. Geren stated that the Board Governance Subcommittee met on September 3, 2015, and recommended publishing these rule changes.

MOTION:

Mr. Geren entertained a motion to approve the proposed rule changes and to direct staff to publish the proposed amendments in the *Texas Register* for public comment.

Motion was made by Mr. Montgomery and seconded by Mr. Margo.

MOTION CARRIED UNANIMOUSLY

8. Proposed Amendments to CPRIT Code of Conduct (TAB 4)

Ms. Doyle stated the proposed changes to the CPRIT Code of Conduct were in the meeting materials and consisted of three non-substantive changes to correct typographical errors.

MOTION:

Mr. Geren entertained a motion to approve the amendments to the CPRIT Code of Conduct.

Motion was made by Mr. Montgomery and seconded by Dr. Rosenfeld.

MOTION CARRIED UNANIMOUSLY

9. Subcommittee Business

Mr. Geren stated at the last OC meeting the committee discussed realigning the subcommittee membership. He proposed that:

- The Nominations Chair and the Presiding Officer work together to reassign Oversight Committee members to different subcommittees based upon their expressed preferences.
- CPRIT staff will communicate the new assignments to all Oversight Committee members.
- The new assignments will be considered interim until the November meeting, when the Oversight Committee will vote to approve the new subcommittee assignments.
- The Oversight Committee establishes the subcommittee realignment as a regular process that is written into CPRIT's Bylaws. The process should be overseen by the Nominations Subcommittee and conducted every two years.

Oversight Committee members should attend their newly assigned subcommittee meetings leading up to the November meeting.

MOTION:

Mr. Geren entertained a motion to approve the process for realigning the membership of subcommittees serving the Oversight Committee.

Motion was made by Mr. Angelou and seconded by Mr. Montgomery.

MOTION CARRIED UNANIMOUSLY

10. Ethics Training

Mr. Geren announced the OC will take up Item 10, Ethics Training, and Item 11, Consultation with General Counsel, together and will seek legal advice in closed session.

Pursuant to Texas Open Meetings Act Section 551.071, the Oversight Committee went into closed session to consult with legal counsel. The following CPRIT staff were asked to join the Oversight Committee in the closed session: Kristen Doyle, Wayne Roberts, Vince Burgess and Cameron Eckel.

Mr. Geren convened in closed session at 12:43 p.m.

Mr. Geren reconvened the open meeting at 1:26 p.m.

11. Consultation with General Counsel

This item was taken up with item 10.

12.	Future Meeting	Dates and Agenda	Items (TAB	18)

Mr. Geren announced that, as agreed at the August OC meeting, the next meeting date will be Thursday, November 19, 2015, at 10:00 a.m.

Signature

13. Adjourn	
MOTION: There being no further business, Mr. Geren entertained a motion to adjourn.	
Motion was made by Mr. Angelou and seconded by Mr. Montgomery. MOTION CARRIED UNANIMOUSL	Y
Meeting adjourned at 1:27 p.m.	

Date



MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER

SUBJECT: AGENDA ITEM 5, CHIEF EXECUTIVE OFFICER REPORT

DATE: NOVEMBER 11, 2015

As of this writing the Chief Executive Officer Report for the November 19, 2015, Oversight Committee will consist of the following items:

- CEO Observations regarding the *Innovations in Cancer Prevention and Research Conference* held on November 9 and 10
- Status of selected CPRIT staff personnel recruitments
- FY 2015 Grant Awards Totals
- Funds available for grant awards in FY 2016

Other topics may be added as warranted.

CPRIT has awarded 915 grants totaling \$1.352 billion

- 146 prevention awards totaling \$142.2 million
- 769 academic research and product development research awards totaling \$1.210 billion

Of the \$1.210 billion in academic research and product development awards:

- 32.5% of the funding (\$393.5 million) supports clinical research projects
- 26.7% of the funding (\$322.8 million) supports translational research projects
- 22.9% of funding (\$276.5 million) supports recruitment awards
- 15.5% of the funding (\$187.9 million) supports discovery stage research projects
- 2.4% of funding (\$29.5 million) supports training programs

CPRIT has 10 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 4 Academic Research
- 3 Product Development Research



MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS

From: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER

Subject: CPRIT ACTIVITIES UPDATE – OCTOBER 2015

Date: OCTOBER 30, 2015

Topics in this update include: Oversight Committee meeting preparations, CPRIT staffing, Legislative and Related Briefings, Compliance Program, Program Updates, Operations (including contracts and audits), Staff Presentations and Meetings, and Subcommittee Meetings.

Preparation for the November Oversight Committee Meeting

The Oversight Committee is scheduled to meet November 19 at 10:00am in the Capitol Extension. The final agenda for the Oversight Committee meeting will be posted by November 11; a tentative agenda is attached. All three programs will have award recommendations to be considered by the Oversight Committee. Other major agenda items include the presentation of four internal audit reports, the FY 2016-2018 internal audit plan, several proposed rule and bylaw changes.

You will receive an email from CPRIT by November 5 with a link and password to access the PIC's recommendations via the grant award portal. The portal has supporting documentation regarding each project proposed for an award, including the application, CEO affidavit, summary statement, and grant pedigree. A summary of the award slate will also be available through the portal. There will be a large number of recommended awards, please allow time to complete the individual conflict of interest checks and review the supporting material.

We plan to distribute the agenda packet to Oversight Committee members electronically by COB November 12. It is our intention to make hard copies of the agenda packet for all members only at the meeting on November 19.

Personnel Changes and Job Openings

CPRIT currently has 32 authorized full-time equivalent (FTE) positions, of which 31 are filled with either permanent or temporary contract personnel.

CPRIT posted the position of Chief Scientific Officer (CSO) on July 28, 2015, and pursuant to the recommendation of our search firm, Spencer Stuart, remains open. Spencer Stuart staff, Lisa Nelson (Operations Manager) and I teleconferenced regularly during the main application and screening process. As previously reported, an organizational meeting of the CSO Interview Committee occurred on June 16. Based upon screening interviews by Spencer Stuart, five candidates were selected for initial in-person interviews conducted by the CSO Interview Committee in Austin on October 26 and 27. Times for a second round of interviews have not been determined as of this writing. The process is designed to have a finalist internally identified by Thanksgiving with a start date in January 2016. Dr. Kripke has graciously agreed to extend her August 31, 2015, retirement date while we are selecting the new CSO.

As reported, the new Chief Product Development Officer is Mike Lang, who started on October 20. Mike has experience founding and serving as chief executive officer of a cancer diagnostic company, serial entrepreneurship, and managing a portfolio for an early stage investment fund. Some of you were involved in the evaluation process and have already met Mike. The rest of you will meet him at the Oversight Committee meeting on November 19. One of Mike's initial assignments is to meet with each member of the Oversight Committee Product Development Subcommittee. In addition, Mike will familiarize himself with existing CPRIT product development grantees, the Product Development Review Council, and investigating options for managing equity-based investments.

We have hired two grant accountants, Shonda Davis and Randy Cunningham. These positions report to Heidi McConnell, Chief Operations Officer.

Spencer Miller-Payne was hired as the new Information Specialist and will start on November 5. He is responsible for conducting and managing the research, writing, and editing of the agency website content in addition to assisting with the writing of health and science content for use in agency publications and reports. He reports to Jeff Hillery, Communications Specialist.

The vacant Administrative Assistant position posting closed and interviews are in progress. In the interim, a contract temporary employee, Sue Cutler, has been retained.

Legislative and Related Briefings

Over September 16-19 I attended a series of events concerning federal childhood cancer research and mitigation in Washington, D.C. These included the Congressional Childhood Cancer Caucus chaired by Congressmen Michael McCaul and Chris Van Hollen and a White House briefing on related presidential initiatives. In addition, I visited SRA International in Frederick, MD to see their facilities and for SRA staff briefings. SRA is our third party grants management contractor.

On October 14, Oversight Committee member Dr. Bill Rice participated in the American Cancer Society Cancer Action Network's Texas Cancer Policy Forum in Austin. Joining Dr. Rice on the panel were Congressman Michael McCaul, Representative Jim Keffer, Matt McManus (President and CEO of Asuragen, a CPRIT product development grantee), cancer survivor Angela Lee, and Nat Jones, a pharmacist representing compounding centers. Similar panels were held in Fort Worth and Houston with other panelists. The one in Houston included Representative Sarah Davis, who requested information from CPRIT for her remarks.

Also, on October 14 I attended the Breast Cancer Awareness event on the Capitol steps hosted by First Lady Cecilia Abbott and the Texas Health & Human Services Commission. In previous years this event was co-hosted by CPRIT but due to gubernatorial administrative staff changes CPRIT was overlooked this year. I have requested that we be involved in future events.

On October 17 I attended the *Texas Tribune's* "Tribfest" conference on The University of Texas campus. This 2 ½ day event was a series of concurrent expert panels on local, state and federal issues. It provided an opportunity to visit with elected officials, media, senior officials with governmental agencies and interested citizens. Although no panels were specific to cancer, CPRIT was brought up briefly and favorably in the session on governmental transparency with University of Texas Regent Wallace Hall and Representative Trey Martinez Fischer.

Compliance Program

Submission Status of Required Grant Recipient Reports

CPRIT Grant Compliance Specialists monitor the status of grantee reports that are currently due. A summary of missing reports is produced by CPRIT's grant management system (CGMS) every week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 530+ grants that are either active or wrapping up grant activities. Grantees submit between 12-15 reports each year per grant project. This means that CPRIT grantees should submit approximately 6,400 reports annually.

As of the most recent CGMS report (October 22, 2015), 23 required grantee reports from 11 entities have not been filed in the system by the set due date. In most cases, CPRIT does not disburse grant funds until the required reports are filed. In some instances, grantee institutions may be ineligible to receive a future award if required reports are not submitted. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to expeditiously resolve filing issues.

FSR Reviews

CPRIT's grant compliance specialists have performed 344 second level reviews of grantee Financial Status Reports (FSRs). CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Desk Reviews

A total of 50 desk reviews have been performed during the first quarter of FY2016 covering nine entities. Desk-based financial monitoring/reviews are conducted during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, procurement and contracting procedures and practices, current and past fiscal audits, subcontracting monitoring, and timeliness of required grantee report submission.

On-site Reviews

CPRIT compliance staff has performed five on-site reviews during the first quarter of FY2016 covering product development research and prevention grant projects. On-site reviews may include examination of the grantee's financial and administrative operations, procurement and contracting policies and procedures, personnel policies and practices, payroll and timesheet policies, travel policies and records, and single audit compliance.

Single Audit Tracking

As part of ongoing monitoring efforts, grant compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend \$500,000 or more in CPRIT grant funds in the grantee's fiscal year must submit a single audit or have an audit performed according to Agreed Upon Procedures. The findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the recipient's fiscal year. Grant compliance specialists are currently working with seven grantees towards resolution of outstanding audit findings.

Scientific Research Program Update

16.1 Academic Research Applications

The 498 applications submitted in response to RFAs that closed on May 20, 2015 were evaluated at the in-person peer review panels from September 29 – October 7 in Dallas. The mechanisms included Research Training Awards, untargeted Individual Investigator Research Awards (IIRA), Individual Investigator Research Awards for Cancers in Childhood and Adolescents (IIRACCA), Individual Investigator Research Awards for Prevention and Early Detection (IIRAP), and Individual Investigator Research Awards for Computational Biology (IIRACB).

The total number discussed was 132, and 65 were recommended for approval. These recommendations were discussed at a Scientific Review Council meeting on October 23, 2015, and 55 applications will come to the November 19 Oversight Committee meeting for action.

16.2 Academic Research Request for Applications and 17.1 Research Request for Applications Applications for High Impact High Risk Grants (HIHR), Core Facilities Support Awards (CFSA), and Multi-Investigator Research Awards (MIRA), and 17.1 Core Facilities Support Awards for Competitive Renewals were submitted on October 13, 2015. These constitute the second and final cycle of awards for FY 2016. We received 153 HIHR, 31, MIRA, 18 CFSA, and 6 CFSA – renewal applications. These will be reviewed during the winter and discussed at the March 2016 peer reviews. These should come to the May 2016 Oversight Committee meeting for action.

16.2 and 16.3 Recruitment Applications

The SRC met on October 19, 2015, to discuss six recruitment applications. They recommended five applications (one Established Investigators, one Rising Stars, and three First-Time Tenure-Track Faculty Awards). The total amount recommended is \$16.0 million. The PIC's award recommendations should come to the Oversight Committee meeting for action in November.

University Advisory Committee (UAC)

The UAC teleconferenced on October 19, 2015, to discuss research program priority recommendations, CPRIT conference participation, and developing outcome metrics that will document CPRIT academic research program accomplishments.

Product Development Program Update

Product Development Cycle 15.4

The Product Development Review Council (PDRC) met on October 12, 2015, to discuss the due diligence reports for three companies. Based upon their review, the PDRC recommended one company be considered for a product development research grant award. The recommendation was forwarded to the chairs of the Program Integration Committee and the Oversight Committee on October 26, 2015.

FY2016 Cycle 16.1

The requests for applications for this cycle were posted on July 16, 2015. Twenty-five applications were submitted by the September 16 deadline. The applications have been assigned to two peer review panels for review. Peer review panel meetings will be held by teleconference on October 29 and 30 to discuss the applications. Based upon the panels' discussion, some of the companies will be invited to make in-person presentations to the panels December 1-4.

Prevention Program Update

FY2016 Review Cycle 1

The Prevention program team revised and released five RFAs in April. One of these RFAs, "Dissemination of CPRIT-funded Cancer Control Initiatives" is a new RFA. Other changes to the RFAs include the addition of the approved program priorities and changes to the areas of emphasis to include screening for Hepatitis B and C for the prevention of liver cancer.

CPRIT received 20 applications by the due date of July 9, 2015. Peer review occurred September 21-22 in Dallas. The Prevention Review Council met by teleconference on October 23; the award recommendations will be presented at the November 19 Oversight Committee.

FY2016 Review Cycle 2

Six RFAs were released on September 24. See, Test & Treat®, a new RFA, is the result of a collaboration between CPRIT and the College of American Pathologists Foundation. A webinar for potential applicants is scheduled for October 21, 2015.

Other Activities

Sixty-six prevention grantee quarterly progress reports were submitted and reviewed.

Communications Update

CPRIT 2015 Conference

Communications activities have centered on the November 9-10, 2015, *Innovations in Cancer Prevention and Research IV* conference. To date 702 people are registered. Four hundred twenty five (425) abstracts were accepted for poster presentations. These and others that were submitted are included in the meeting program. Graphic design, printing and décor activities are underway.

Conference promotion included use of the CPRIT website, social media channels, our listserv and media outreach. In October, the *Austin Business Journal* ran a Q&A style story with me on the conference.

CPRIT Messages

- The quarterly achievements report is being redesigned for FY 2016. A new report will be available after the November 19 Oversight Committee meeting.
- A story about CPRIT and its product development research program appeared in the *Dallas Morning News* on September 25.

• The Communications team is updating the message platform and developing plans for the upcoming year to include a tour in late January or February and the preparation of materials for the upcoming legislative session.

Social Media

The Communications team continues to use social media outreach, including Twitter and Facebook, to publicize CPRIT-generated content along with news and information about and from grantees, advocates and other trusted sources.

Operations and Finance (Contracts, RFPs, Audit)

Financing Request

On October 29 the Texas Public Finance Authority issued \$369.8 million in General Obligation and Refunding Bonds on behalf of CPRIT. This transaction included refunding \$300 million of General Obligation Commercial Paper Notes issued on behalf of CPRIT during the past year and \$69.8 million in General Obligation Bonds for the agency's projected funding needs for December 2015.

Audits

Our outsourced internal auditor, Weaver and Tidwell, completed the four scheduled audit reports for FY 2015. These reports include a grants management audit, expenditure audit, follow up procedures on prior findings in governance and information technology, and follow up procedures on prior findings of grantee monitoring audits. These reports will be presented at the Oversight Committee meeting in November. Weaver and Tidwell also updated the agency's risk assessment with input from staff to develop the audit plan for FY 2016. Weaver and Tidwell has developed a three-year audit plan (FY 2016 through FY 2018) for long range planning. This plan will also be discussed at the Audit Subcommittee meeting on November 6 and presented to the Oversight Committee for consideration on November 19.

We held a planning meeting with our financial auditor, McConnell & Jones, on October 12 for the financial audit covering FY 2015. You should have received an email request from Heidi McConnell to complete Related Party and Fraud Risk questionnaires for this audit and return them to Mr. Imran Khimani at McConnell & Jones. The auditor's staff will conduct field work at CPRIT during the week of November 2. This audit report is due by December 20 to the Comptroller's Office.

Contracts

On October 26, the Legislative Budget Board issued approval of two FY 2016 service contracts the Oversight Committee approved at your August 19 meeting. One is with ICON Clinical Research for business-regulatory due diligence evaluation of product development applications and the other is with CohnReznick for grant compliance monitoring services.

Staff Presentations/Meetings/Training

- I appeared on *Capital Tonight* with Paul Brown on September 14 to discuss agency developments since my last appearance.
- Kristen Doyle and I attended the Spindletop Capital Annual Meeting in Houston on September 29. At this meeting, companies recently receiving Spindletop investment funding made status reports on their activities. Several featured innovative cancer-related projects.
- Dr. Garcia was invited to be the keynote speaker at a health fair event, "Dia de la Mujer",
 October 3 sponsored by Telemundo Amarillo. The event attracted over 500 women. Dr.
 Garcia delivered her keynote address in Spanish.

Upcoming Standing and Special Oversight Committee-related Meetings

The dates and times for the upcoming subcommittee meetings are listed below. Several regular subcommittee meeting times were changed to accommodate the CPRIT conference. When the day and/or meeting time is different than the regularly scheduled time, it is noted below as "new time"

Board Governance – November 4 at 3:00 pm (new time)

Audit – November 6 at 2:30 pm (new time)

Prevention – November 13 at 1:00 pm (new time)

Scientific Research – November 11 at 10:00 am Product Development – November 12 at 10:00 am Nominations – November 13 at 10:30 am

An agenda, call-in information and supporting material will be sent to the subcommittees one week prior to the meeting date. If you or your assistant did not receive a calendar invite from CPRIT staff for subcommittee meeting dates in November, please contact Mary Gerdes at mgerdes@cprit.state.tx.us.

CPRIT has awarded 919 grants totaling \$1.360 billion

- 146 prevention awards totaling \$142.2 million
- 773 academic research and product development research awards totaling \$1.217 billion

Of the \$1.217 billion in academic research and product development awards,

- 31.6% of the funding (\$385.1 million) supports clinical research projects
- 26.5% of the funding (\$322.8 million) supports translational research projects
- 24.1% of funding (\$292.2 million) supports recruitment awards
- 15.4% of the funding (\$187.9 million) supports discovery stage research projects
- 2.4% of funding (\$29.5 million) supports training programs.

CPRIT has 9 open Requests for Applications (RFAs)

- 3 Academic Research Recruitment
- 6 Prevention

CPRIT MANAGEMENT DASHBOARD FISCAL YEAR 2015

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (YTD)
ACCOUNTABILITY													,	` /
Announced Grant Awards			32			58		2	4			6	102	
New Grant Contracts Signed	11	14	47	19	21	7	14	18	40	13	22	10	236	
New Grant Contracts In			26			45			2			19	92	
Grant Reimbursements Processed	2	434	0	11	109	43	30	512	94	87	75	284	1681	
Grant Reimbursements Processed	\$ 3,919,524	\$ 30,454,155	\$ -	\$ 2,501,374	\$ 10,721,494	\$ 3,217,173	\$ 3,528,675	\$ 39,082,905	\$ 5,898,037	\$ 7,717,815	\$ 29,372,499	\$ 23,390,768	\$ 159,804,420	
Revenue Sharing Payments	\$ 1,000	\$ -	\$ -	\$ 7,456	\$ 6,208	\$ 10,241	\$ -	\$ 4,500	\$ 8,041	\$ -	\$ 1,000	\$ 8,327	\$ 46,774	\$ 2,213,516
Total Value of Grants Contracted	\$ 8,316,567	\$ 21,311,777	\$43,594,810	\$ 14,713,321	\$ 23,311,979	\$ 111,151,038	\$ 24,396,331	\$ 23,877,607	\$ 73,478,836	\$ 75,095,047	\$ 32,309,974	\$ 18,277,304	\$ 469,834,591	
Grants Awarded (#)/ Applications Rec'd (#)	12%	12%	12%	12%	12%	13%	13%	13%	12%	12%	11%	12%		
Debt Issued (\$)/Funding Awarded	51%	51%	53%	53%	53%	49%	49%	58%	54%	60%	60%	59%		
Grantee Compliance Trainings/Monitoring Visits	1	1	0	0	2	2	2	6	1	3	2	2	22	
Awards with Delinquent Reimbursement Submission (FSR)						9			1			1		
Awards with Delinquent Matching Funds Verification			16			2			68			16		
Awards with Delinquent Progress			10			14			4			7		
Report Submission IA Agency Operational														
Recommendations Implemented	2	3	6	6	7	8	8	8	8	8	8	13		
IA Agency Operational Recommendations In Progress	13	12	9	9	8	7	7	7	7	7	7	2		
IA Grantee Recommendations Implemented	0	1	1	1	1	1	1	1	1	1	1	19		
IA Grantee Recommendations In Progress	20	19	19	19	19	19	19	19	19	19	19	1		
Open RFAs	7	13	10	10	6	11	8	13	13	8	8	10		
Prevention Applications Received	0	0	0	35	0	0	0	0	0	0	20	0	55	560
Product Development Applications Received	0	0	0	0	0	16	0	0	0	0	0	0	16	268
Research Applications Received	10	0	161	2	4	4	12	9	514	7	5	2	730	4,513
Help Desk Calls/Emails	230	240	210	184	149	171	144	217	371	192	186	183	2,477	
Magazon														
MISSION RESEARCH PROGRAM														
Number of Research Grants														
Awarded (Annual)			7			54		2	4			6	73	
Recruited Scientists Announced														135
Recruited Scientists Accepted														95
Recruited Scientists Contracted														83
Published Articles on CPRIT- Funded Projects (#)													1,087	
Jobs Created & Maintained (#)													2,528	
Trainees in CPRIT-Funded Training Programs (#)													255	
Open Clinical Trials (#)														53

CPRIT MANAGEMENT DASHBOARD FISCAL YEAR 2015

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (YTD)
Number of Patents Resulting from Research													50	
Number of Patent Applications													54	
Number of Investigational New													26	
Drugs														
PRODUCT DEVELOPMENT														
PROGRAM														
Number of Product Development Grant Awarded (Annual)			20			4			2			0	26	
Life Science Companies Recruited													5	7
Published Articles on CPRIT- Funded Projects													5	
Number of Jobs Created & Maintained													190	
Open Clinical Trials (#)														7
Number of Patents Resulting from Research													8	
Number of Patent Applications													6	
Number of Investigational New Drugs													1	
PREVENTION PROGRAM														
Number of Prevention Grant Awarded (Annual)			5			0			11			0	16	
People Served by CPRIT-Funded Prevention and Control Activities			178,669			165,145			175,123			113,906	632,843	
People Served through CPRIT- Funded Education and Training			46,399			42,535			48,268			43,070	180,272	
People Served through CPRIT- Funded Clinical Services			132,270			122,610			126,855			70,836	452,571	
- university of the state of th														
TRANSPARENCY														
Total Website Hits (Sessions)	6,610	7,275	8,202	5,101	5,844	9,735	7,612	8,525	9,515	6,093	7,320	6,978	88,810	
Total Unique Visitors to Website (Users)	4,811	5,143	5,628	3,852	4,195	6,625	5,420	5,983	6,228	4,440	5,062	4,756	62,143	



MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: MARGARET KRIPKE, PH.D., CHIEF SCIENTIFIC OFFICER

SUBJECT: UPDATE OF RESEARCH ACTIVITIES

DATE: NOVEMBER 5, 2015

Research Grants

16.1 Research Applications

The 498 applications submitted in response to the round of RFAs that closed on May 20, 2015 were discussed at the in person peer review panel meetings from September 29 – October 7 in Dallas. The mechanisms included Research Training Awards, untargeted Individual Investigator Research Awards (IIRA), Individual Investigator Research Awards for Cancers in Childhood and Adolescents (IIRACCA), Individual Investigator Research Awards for Prevention and Early Detection (IIRAP), and Individual Investigator Research Awards for Computational Biology (IIRACB). The total number of applications discussed was 132, and 65 were recommended. These panel recommendations were be discussed at a Scientific Review Council meeting on October 23, 2015, and 55 will come to the November 19th Oversight Committee meeting for approval.

16.2 Research Request for Applications and 17.1 Research Request for Applications
Applications for High Impact High Risk Grants (HIHR), Core Facilities Support Awards (CFSA), and Multi-Investigator Research Awards (MIRA), and 17.1 Core Facilities Support Awards for Competitive Renewals were submitted on October 13, 2015. These will constitute the second and final cycle of awards for FY 16. We received 153 HIHR, 31, MIRA, 18 CFSA, and 6 CFSA – renewal applications for a total of 208 applications. Two HIHR applications were withdrawn for exceeding institutional limits. Two hundred six applications have been assigned to peer review panels and will be reviewed during the winter and discussed at the March 9-16, 2016 peer review meetings. These applications will come to the May 2016 OC meeting for approval.

16.2 and 16.3 Recruitment Applications

The SRC met on October 19, 2015 to discuss six recruitment applications. They recommended five applications (one Recruitment of Established Investigators, one Recruitment of Rising Stars (RRS), and three Recruitment of First-Time Tenure-Track Faculty (RFT) Awards). The total amount of the grants is \$16M. These will come to the November OC meeting for approval.

<u>University Advisory Committee (UAC) and Advisory Committee for Childhood Cancer (ACCC) Meetings</u>
The UAC met in a breakout session during the CPRIT conference on November 10, 2015 to discuss the status of the Research and Recruitment Grant Programs (peer review, awards, application

submissions, and program priorities), the committee's annual report, and the development of outcome metrics that will assist CPRIT in promoting the accomplishments of the grant programs.

The ACCC met in a breakout session during the CPRIT conference on November 9, 2015 to discuss the status of the Research and Recruitment Grant Programs (peer review, awards, application submissions, and program priorities), the committee's annual report, and expanding the membership of the committee to include additional institutions.



MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: REBECCA GARCIA, PHD, CHIEF PREVENTION AND

COMMUNICATIONS OFFICER

SUBJECT: PREVENTION PROGRAM UPDATE

DATE: NOVEMBER 4, 2015

The following report provides an overview of the Prevention Program activities from August 2015 through November 2015.

FY2016 Review Cycle 1:

We revised and released 5 RFAs in April, one of which was new. The new RFA is titled "Dissemination of CPRIT-funded Cancer Control Initiatives." Other changes to the RFAs included the addition of the approved program priorities and changes to the areas of emphasis to include screening for Hepatitis B and C for the prevention of liver cancer.

We received 20 applications by the due date of July 9, 2015. Peer review took place Sept 21-22 in Dallas. The Prevention Review Council met on October 23 via teleconference. Award recommendations will be presented at the November 19, 2015 Oversight Committee.

FY2016 Review Cycle 2:

Six RFAs were released on Sept. 24. See, Test & Treat® (STT), a new RFA, is the result of a collaboration between CPRIT and the College of American Pathologists (CAP) Foundation. A webinar for potential applicants is scheduled for October 21, 2015.

Other Activities:

Sixty-six grantee quarterly progress reports were submitted and reviewed.

I was invited to be the keynote speaker at a health fair event, "Dia de la Mujer", October 3 sponsored by Telemundo Amarillo. The event attracted over 500 women.



MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER

FROM: KRISTEN DOYLE, GENERAL COUNSEL AND DEPUTY EXECUTIVE

OFFICER

SUBJECT: CONTRACT EXTENSION—PP120029

DATE: NOVEMBER 12, 2015

Summary and Recommendation

I recommend that the Oversight Committee authorize Mr. Roberts to approve a contract extension for up to six months for grant award PP120029. The contract extension is necessary so that Department of State Health Services (DSHS) may use remaining grant funds to pay for an independent audit required by CPRIT's award contract. The request comes before the Oversight Committee because DSHS failed to request a contract extension within the time period specified by CPRIT's administrative rules.

Background

The Department of State Health Services (DSHS) was awarded a grant March 1, 2012 to provide telephone cessation counseling and nicotine replacement therapy through the state's Quitline. This summer CPRIT staff reviewed the file for PP120029 during the course of CPRIT's multiphased, comprehensive report reconciliation project and determined that two independent audit reports (for the second and third years of the grant project) were not filed with CPRIT as required by DSHS's contract.

Grantees that expend \$500,000 or more in state grants during the grantee's fiscal year must submit an annual single independent audit, a program specific audit independent audit, or an agreed upon procedures engagement. In its first year of the grant project, DSHS relied upon the statewide single audit performed by the State Auditor's Office to fulfill CPRIT's audit requirement. However, following the CPRIT's State Audit, CPRIT notified all grantees in November 2013, of new audit requirements. As a result of the changed requirements, submission of the State Auditor's statewide single audit report no longer met the independent audit requirement for CPRIT grantees.

On July 27, 2015, CPRIT contacted DSHS seeking the missing independent audit reports. DSHS and CPRIT discussed the missing reports and clarified that DSHS was required to fulfill the

independent audit requirement. CPRIT's administrative rule T.A.C. § 703.13(c) prohibits reimbursement of grant award funds until the grantee submits the delinquent audit report. Accordingly, on September 2, 2015, CPRIT notified DSHS that it was holding the reimbursement owed to DSHS for costs incurred in the March – May 2015 time period until the required audits are submitted.

Discussion

Texas Uniform Grant Management Standards (UGMS) allows grantees to use grant funds to cover costs associated with the single audit requirement. DSHS has remaining grant funds sufficient to cover the cost of the audit; however, DSHS's grant contract ended on August 28, 2015, before DSHS was able to draw down grant funds. CPRIT's administrative rules provide a process for grantees to extend the contract end date, but DSHS did not submit a request in time for CPRIT staff to act upon it.

CPRIT staff do not retain the authority to approve the contract extension pursuant to our established process because of the late request. The Oversight Committee is statutorily responsible for approving grant contracts and has the authority to authorize an extension of time associated with a grant contract it has approved. Extending the contract end date allows DSHS to access grant funds necessary to complete the required audits.

If the no cost extension is not approved, DSHS would be required to pay for the audit using other funds. If DSHS is unable to do so or elects not to do so, it will waive reimbursement for the last two fiscal quarters of its grant project. DSHS will also be barred from receiving a CPRIT grant award in the future until it submits the outstanding audits.

Recommendation

I recommend that the Oversight Committee authorize Mr. Roberts to approve a no cost extension for the DSHS contract that changes the termination date of the contract to February 28, 2016. Approving the contract extension allows DSHS to access grant funds to complete the required audits, an important monitoring tool for CPRIT.



MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS

From: MICHAEL LANG, CHIEF PRODUCT DEVELOPMENT OFFICER

Subject: PRODUCT DEVELOPMENT UPDATE

NOVEMBER 12, 2015

Award Contracts

One product development grant contract for a project approved in 2014 has not yet been executed. The contract for OncoNano Medicine, Inc. is pending approval of a contract amendment related to an IP issue. The contract is expected to be signed next week.

Proposed Awards – Cycle 15.4

Following in-person presentations in April, the Product Development Research peer review panel recommended three applications for due diligence. Intellectual property and business due diligence was completed for the three applicants by September. The Product Development Review Council (PDRC) met to consider the due diligence reports on October 12. After discussion, the PDRC decided to recommend one company for consideration of a grant award. The PDRC's recommendation is contingent upon the company successfully addressing certain identified issues prior to contract execution. The Program Integration Committee met November 3 and approved the PDRC recommendation. The Product Development Subcommittee met November 12 to discuss the award proposal. The Subcommittee recommends the Oversight Committee approve the grant award subject to certain contract conditions. The recommendation will be considered by the Oversight Committee at its meeting on November 19.

Award Cycle 16.1

Three RFAs (for new, established, and relocating companies) for Product Development Research award cycle 16.1 were released on July 6. Twenty-five company applicants submitted proposals by September 16, 2015. Of the 25 applicants, eight applicants are from out of state. Seven applications were submitted by companies that have completed at least their Series A fundraising round. The remaining 18 companies are considered new company applicants.

The applications were assigned to expert reviewers for individual review and scoring. The Product Development review panels met on October 29 and 30 to consider the reviews. Based upon the discussions and the reviewer scores, the review panels will invite twelve applicants to make inperson presentations to the review panel meetings held in Dallas the first week of December. Applications recommended for awards are expected to be considered at the May 2016 Oversight Committee meeting.

Grantee Progress

Since the last Oversight Committee meeting in September, a number of CPRIT product development grantees have made news for promising collaborations and early results.

- Asuragen (2012, \$6.8 mil) presented extensive new data in two corporate workshops at the Association for Molecular Pathology Annual Meeting on November 4, 2015. The corporate workshops will focus on next generation sequencing (NGS)-based assays for pan cancer and lung cancer diseases, as well as a new BCR-ABL monitoring assay for Chronic Myeloid Leukemia. Products and technologies developed by Asuragen, a global molecular diagnostics company, will also be featured in 11 scientific posters, at sessions on genetics, informatics, solid tumors, and technical topics. Asuragen's CEO, Matt McManus, will moderate the "Early Successes" panel at CPRIT's conference on November 10.
- In October Immatics US, Inc. (2015, \$19.7 mil) and UTHealth announced a collaboration on cellular manufacturing for adoptive cellular therapy clinical trials. Immatics manufacturing personnel and UTHealth quality assurance experts will work together for therapeutic T cell production through the end of 2018. The T cells will treat cancer patients with high unmet clinical need in two early-stage CPRIT funded clinical trials at MD Anderson under the recently announced collaboration between Immatics and MD Anderson. Harpreet Singh, PhD, Immatics U.S. CEO, will highlight these collaborations during the "University and Biotech Company Alliances" panel at CPRIT's conference on November 10.
- In early October, **ESSA Pharma Inc**. (2014, \$12 mil) reported that the FDA approved its investigational new drug application for a Phase 1/2 clinical trial for treatment of metastatic castration-resistant prostate cancer in patients who are not helped by current treatments.
- **DNAtrix, Inc.** (2014, \$10.8 mil) announced an oncology Phase II clinical study collaboration with Merck to study DNAtrix's immunotherapy in combination with Merck's anti-PD-1 therapy for patients with recurrent glioblastoma. In their early October announcement, DNAtrix reports that the potential anti-tumor effect of combining the two immunotherapies may advance care for patients with this aggressive cancer.
- Cell Medica (2012, \$15.6 mil) was named one of *Fierce Biotech's* "2015 Fierce Fifteen" companies for its bifurcated approach to handling cell therapy using the patient's own T cells to target cancerous antigens and infusing donor T cells into immunosuppressed patients. Cell Medica is currently working through a Phase II clinical trial in lymphoma.

CPRIT's 2015 Biannual Innovations Conference

<u>CPRIT's 2015 Biannual Innovations Conference</u> will be held in Austin on November 9-10. We have been fortunate to be assisted by several members of the Texas life sciences community who are excited about the opportunity to showcase the work that CPRIT and oncology companies are doing in Texas. We will have five segments dedicated to Product Development issues. These include:

- Elements of a Successful Product Development Application
- Resources for Texas BioScience Companies Part I Incubators
- Resources for Texas BioScience Companies Part II Investors
- University and Early Stage Company Alliances
- CPRIT Companies in Action: Early Stage Successes (1.5 hours)



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

November 16, 2015

Oversight Committee Members,

Pursuant to 25 T.A.C. § 703.7(j), I request that the Oversight Committee approve authority for CPRIT to advance grant funds upon execution of a grant contract for one company that will be considered for Product Development grant awards at the November 19, 2015, Oversight Committee meeting. The company has been recommended for a grant award by the Program Integration Committee (PIC). The Oversight Committee will consider the PIC's recommendation at the November 19, 2015, Oversight Committee meeting.

Although CPRIT disburses the majority of grant funds pursuant to requests for reimbursement, CPRIT may disburse grant funds in advance payments consistent with the General Appropriations Act, Article IX, § 4.03(a). Typically, the grant amount to be paid in advance is based upon the project year budget or tranche amount. All grant recipients, including those that receive advance payment of grant funds, are required to submit quarterly financial status reports that are reviewed and approved by CPRIT's financial staff. Failure to submit the financial status reports on a timely basis will result in forfeiture of reimbursement for expenses for the quarter and may result in grant termination and repayment of grant funds.

After consultation with Mr. Michael Lang, CPRIT's Chief Product Development Officer, the following reason supports advance payment of grant funds for the company: pre-clinical trial contracts will need to be entered into with substantial upfront payments.

Sincerely,

Wayne R. Roberts,

CPRIT Chief Executive Officer



SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE MEMBER NOMINATIONS

Product Development Research Program

- Herbert I. Hurwitz, M.D.
- Vivian Lee (Advocate Reviewer)
- Marcia Dougan Moore, MPH

Academic Research Program

• Gurinder S. Atwal, PhD

BIOGRAPHICAL SKETCH								
NAME Herbert I. Hurwitz, M.D.	POSITION Associate P	TITLE Professor of Me	edicine					
eRA COMMONS USER NAME hurwi004 EDUCATION/TRAINING (Begin with baccalaureate	e or other initial	r other initial professional education, such as nursing						
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY					
Brandeis University, Waltham, MA	BA	1984	Biochemistry					
Jefferson Medical College of Thomas Jefferson University, Philadelphia, PA	MD	1988	Medicine					
Johns Hopkins University School of Medicine and School of Hygiene and Public Health, Baltimore, MD	MS	1997	Clinical Investigation					

A. Personal statement: I am the clinical director of the Duke Phase I and GI Oncology Clinical Research programs at the Duke Cancer Institute. I have been the PI of over 75 phase I-III studies, the majority of which are investigator initiated. I was the lead investigator on the phase III study of IFL chemotherapy +/-bevacizumab (Avastin), which lead to bevacizumab's initial FDA approval. I am the correlative science lead for blood based biomarkers on CALGB80405. My research has focused on the mechanisms of action and toxicity for novel targeted anti-cancer therapies, particularly anti-angiogenesis agents. Our group has developed a novel blood based multiplex analysis of over 50 proteins related to tumor angiogenesis and tumor growth. Our lab serves as the core lab for multiplex ELISA analyses for Alliance and we have now run this profile on several phase III CALGB study with bevacizumab, including studies in pancreatic and renal cell cancer. I serve as a member of the GI and GI translational committees of Alliance and a board member of ACCRU. I have mentored over 12 fellows and 15 junior faculty members and have had K23, K24, R21, R01, and now UM1 funding.

B. Positions and Honors.

Professional training and academic career

1988-1991	Residency in Internal Medicine, Michael Reese Hospital, Chicago, IL.
1992-1996	Clinical Fellow in Oncology, Johns Hopkins University School of Medicine and School of
	Hygiene and Public Health Johns Hopkins Oncology Center, Baltimore, MD.
1994-1996	M.S. in Clinical Investigation, Johns Hopkins University School of Medicine and School of
	Hygiene and Public Health, Baltimore, MD.
1996-1997	Associate in Oncology, Johns Hopkins Oncology Center, Baltimore, MD.
1997-2004	Assistant Professor of Medicine,
	Clinical Director, Duke Phase 1 Program, DUMC
	Co-Leader, GI Oncology Program in development, DUMC
	Director, Glaxo Wellcome – Oncology Duke Drug Development Fellowship
2004-2012	Associate Professor of Medicine
	Duke University Medical Center (DUMC), Durham, NC
2012-present	Professor of Medicine
	Duke University Medical Center (DUMC), Durham, NC

Honors

Brandeis Research Stipend
Cum laude, Brandeis University
Jacob and Bella Thurman Award for Social Citizenship
Dean's list 1980-84, Brandeis University
NIH Research Stipend
Rhone-Poulenc Rorer Travel Award, AACR annual meeting
Sandoz Faculty Scholar, Duke University Medical Center

C. Selected peer-reviewed publications (in chronological order). (From over 57 publications)

- 1. Kabbinavar F, **Hurwitz HI**, Fehrenbacher L, Meropol NJ, Novotny WF, Lieberman G, Griffing S, Bergsland E. Phase II, randomized trial comparing bevacizumab plus fluorouracil (FU)/leucovorin (LV) with FU/LV alone in patients with metastatic colorectal cancer. *Journal of Clinical Oncology*. 21(1):60-5, 2003 Jan 1.
- 2. Lockhart AC, Braun RD, Yu D, Ross JR, Dewhirst MW, Klitzman B, Yuan F, Grichnik JM, Proia AD, Conway DA, Mann G, **Hurwitz H**I. A clinical model of dermal wound angiogenesis. *Wound Repair & Regeneration*. 11(4):306-13, 2003 Jul-Aug.
- 3. Lockhart AC, Braun RD, Yu D, Ross JR, Dewhirst MW, Humphrey JS, Thompson S, Williams KM, Klitzman B, Yuan F, Grichnik J, Prioa A, Conway D, **Hurwitz HI**. Reduction of Wound Angiogenesis in Patients Treated with BMS-275291, a Broad Spectrum Matrix Metalloproteinase Inhibitor. *Clinical Cancer Research*. 9:586-593, 2003.
- 4. **Hurwitz** HI, Fehrenbacher L, Meropol NJ, Novotny WF, Lieberman G, Griffing S, Bergsland E. Phase II, randomized trial comparing bevacizumab plus fluorouracil (FU)/leucovorin (LV) with FU/LV alone in patients with metastatic colorectal cancer. *Journal of Clinical Oncology*. 21(1):60-5, 2003 Jan 1.
- 5. **Hurwitz H**, Fehrenbacher L, Novotny W, Cartwright T, Hainsworth J, Heim J, Berlin J, Baron A, Griffing S, Holmgren E, Ferrara N, Fyfe G, Rogers B, Ross R, Kabbinavar F. Addition of Bevacizumab (rhuMAb VEGF) to Bolus IFL in the First-Line Treatment of Patients with Metastatic Colorectal Cancer: Results of a Randomized Phase III Trial. *New England Journal of Medicine*. 350: 23-30; June 3, 2004.
- 6. Ince WL, Jubb AM, Holden SN, Holmgren EB, Tobin P, Sridhar M, **Hurwitz HI**, Kabbinavar F, Novotny WF, Hillan KJ, Koeppen H Association of k-ras, b-raf, and p53 status with the treatment effect of bevacizumab. *J Natl Cancer Inst.* 97(13):981-9 2005 Jul 6.
- 7. Scappaticci, FA, Fehrenbacher L, Cartwright T, Hainsworth J, Heim W, Berin J, Kabbinavar F, Novotny W, Sarkar S, **Hurwitz H**. Surgical wound healing complications in metastatic colorectal cancer patients treated with bevacizumab. *J. Surg. Oncology*. 91:173-180, 2005.
- 8. **Hurwitz H**, Kabbinavar F. Bevacizumab combined with standard fluoropyrimidine-based chemotherapy regimens to treat colorectal cancer. *Oncology*. 69 Suppl 3:17-24, 2005.
- 9. Jubb AM, **Hurwitz HI**, Bai W, Holmgren EB, Tobin P, Guerrero AS, Kabbinavar F, Holden SN, Novotny WF, Frantz GD, Hillan KJ, Koeppen H. Impact of vascular endothelial growth factor-A expression, thrombospondin-2 expression, and microvessel density on the treatment effect of bevacizumab in metastatic colorectal cancer. *Journal of Clinical Oncology*. 24(2):217-27, 2006 Jan 10.
- 10. Scappaticci FA, Skillings JR, Holden SN, Gerber HP, Miller K, Kabbinavar F, Bergsland E, Ngai J, Holmgren E, Wang J, **Hurwitz H**. Arterial thromboembolic events in patients with metastatic carcinoma treated with chemotherapy and bevacizumab. *Journal of the National Cancer Institute*. 99(16):1232-9, 2007 August 15.
- 11. **Hurwitz HI**, Yi J, Ince W, Novotny W, Rosen O. The Clinical Benefit of Bevacizumab in Metastatic Colorectal Cancer Is Independent of K-ras Mutation Status: Analysis of a Phase III Study of Bevacizumab with Chemotherapy in Previously Untreated Metastatic Colorectal Cancer. *The Oncologist*, 2009: 14:000-000, 2009 Jan 14.
- 12. Facemire CS, Nixon AB, Griffiths R, **Hurwitz H**, Coffman TM. Vascular endothelial growth factor receptor 2 controls blood pressure by regulating nitric oxide synthase expression. *Hypertension*. 54(3):652-8, 2009 Sept.
- 13. **Hurwitz HI,** Saltz LB, Van Cutsem E, Cassidy J, Wiedemann J, Sirzen F, Lyman GH, Rohr UP. Venous thromboembolic events with chemotherapy plus bevacizumab: a pooled analysis of patients in randomized phase II and III studies. *Journal of Clinical Oncology*. 29(13):1757-64, 2011 May.
- 14. Innocenti F, Owzar K, Cox NL, Evans P, Kubo M, Zembutsu H, Jiang C, Hollis D, Mushiroda T, Li L, Friedman P, Wang L, Glubb D, **Hurwitz H**, Giacomini KM, McLeod HL, Goldberg RM, Schilsky RL, Kindler HL, Nakamura Y, Ratain MJ. A genome-wide association study of overall survival in pancreatic cancer patients treated with gemcitabine in CALGB 80303. *Clin Cancer Res.* 18(2):577-84. 2012 Jan 15.

- 15. Nixon AB, Pang H, Starr M, Friedman PN, Bertagnolli MM, Kindler HL, Goldberg RM, Venook AP, and Hurwitz HI. Prognostic and predictive blood-based biomarkers in patients with advanced pancreatic cancer: Results from CALGB 80303 (Alliance). *Clin Cancer Res* 2013;19:6957-6966.
- **D. Research Support.** List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and your role (e.g. PI, Co-Investigator, Consultant) in the research project. Do not list award amounts or percent effort in projects.

1UM1-CA186704-01 (H Hurwitz, PI) "Duke-UNC-Wash U Partnership for Early Phase Clinical Trials in Cancer". Goals: To design and oversee novel early stage oncology therapeutic clinical trials within the ECTN (Early Clinical Trials Network) of the NCI.

1R01-CA112252-01A1 (H Hurwitz, PI) "Anti-VEGF in tumors & Wounds: Efficacy vs. Toxicity". Goals: To evaluate the similarities and differences in baseline angiogenic factor expression and the changes in these profiles in response to treatment with bevacizumab in patients with metastatic GI cancers, using pre-treatment and on-treatment tumor biopsies and dermal wound biopsies.

1K24-CA113755-01A1 (H Hurwitz, PI) "Wound Angiogenesis as a Biomarker for Tumor Angiogenesis". Goals: To explore similarities of tumor and wounds in preclinical and clinical settings, to provide mentoring to junior investigators, and to advance other aspects of mid-career development.

Industry sponsored and investigator initiated studies Over 75 studies. Please see other support.

BIOGRAPHICAL SKETCH								
NAME POSITION TITLE								
Vivian Lee	Vivian Lee Patient/Research Advocate							
	EDUCATION/TRAIN	ING						
INSTITUTION AND LOCATION	DEGREE	YEAR(S)	FIELD OF STUDY					
Harvard University Cambridge, MA	AB cum laude in general studies	1977-1981	Biochemistry					

A. PERSONAL STATEMENT

A breast cancer survivor since 2000, Vivian is a Susan G. Komen Advocate In Science, as well as a member of the Breast Science Advocacy Core (BSAC) in the UCSF Breast Oncology Program. She has served as a Consumer Reviewer for the US Department of Defense (DoD) Breast Cancer Research Program, and as a National Patient Navigation Grant reviewer for Susan G. Komen. Vivian collaborates with research investigators at various academic institutions to provide patient perspective in shaping grant and award applications to, and research projects funded by, DoD, California Breast Cancer Research Program, Susan G. Komen, Sidney Kimmel Foundation, ASCO's Conquer Cancer Foundation and Patient-Centered Outcomes Research Institute (PCORI).

Vivian is an advocate advisor to the University of California's Athena Breast Health Network, providing patient input for its WISDOM Trial on personalized breast cancer screening, for which Athena has been awarded a \$14 million Pragmatic Clinical Studies grant by PCORI. Vivian is a member of the Community Profile Committee and Grants Committee of Komen San Francisco Bay Area, for which she has also served as a community grant peer reviewer. She is a member of the Scientific Advisory Committee of the 7th International Breast Density and Breast Cancer Risk Assessment Workshop. Vivian mentors newly diagnosed patients, providing emotional support, peer mentoring and patient networking resources.

B. PROFESSIONAL

1983 - Present	Founder and Managing Director Aqua Partners LLC (Life science industry strategic advisory), New York / Palo Alto		
2000 – 2005	Advisor, Venture Partner Global Biomedical Partners (Life science private equity fund), New York / Zurich		
2003 – 2005	Board of Directors Innodia, Inc. (Diabetes drug development), Montreal, Canada		
2003 – 2005	Board of Directors Syntonix Pharmaceuticals Inc. (Pulmonary drug delivery technology), Waltham, MA		
1981 – 1983	Business Analyst, Office of New Ventures WR Grace & Co. (Fortune 50 diversified chemical conglomerate), New York, NY		
Research Training			
1978-1981	(Sept-June) Department of Tumor Immunology, Dana Farber Cancer Institute, Boston, MA Conducted research on suppressor T cell surface antigens		
1978-1981	(June-Sept) Department of Pathology, Yale University School of Medicine, New Haven, CT Conducted research on suppressor T cell surface antigens		
1975-1977	Department of Human Genetics, Yale University School of Medicine, New Haven, CT Literature research and data entry for familial genetics studies		

C. RESEARCH ADVOCACY EXPERIENCE

Advocate collaborator with clinicians/researchers at:

- Stanford University
- Cornell University
- University of California, Berkeley
- University of California, Riverside
- University of California, San Francisco

Cancer Advocacy Training

UCSF Breast Oncology Program Scientific Retreat, San Francisco, CA
Personalized Medicine World Conference – Silicon Valley, Mountain View, CA
Breast Cancer and the Environment Research Program Annual Meeting, San Francisco, CA
University of California Athena Breast Health Network - Fall Retreat, Irvine, CA
New Approaches to Cancer Drug Discovery: 2014 Global Discovery Symposia, San Francisco
California Partnership for Access to Treatment (CPAT) - Cancer: Diverse Populations and
Treatment Innovations Seminar
Research Advocacy Network (RAN) Focus on Research Scholar
ASCO Annual Meeting, Chicago, IL
UCSF Breast Oncology Program Seminar: Risk Assessment for Breast Cancer: Past, Present, and
Future Implications for Care
University of California Athena Breast Health Network - Winter Retreat, San Francisco, CA
UCSF Breast Oncology Program Scientific Retreat, San Francisco, CA
Personalized Medicine World Conference – Silicon Valley, Mountain View, CA
UCSF Breast Oncology Program Roundtable: Successful Funding and Research Through Advocate
Collaboration
Breast Cancer Connections 10 th Annual Breast Cancer Conference, Redwood Shores, CA
ASCO Breast Cancer Symposium, San Francisco, CA
Completed Cochrane US Project online course: Translating Critical Appraisal of a Manuscript into
Meaningful Peer Review
Sixth International Workshop on Breast Density and Breast Cancer Risk Assessment, San
Francisco, CA
California Breast Cancer Research Symposium, Costa Mesa, CA
Fourth Annual Stanford Women's Health Forum, Palo Alto, CA
Breast Cancer Connections 9 th Annual Breast Cancer Conference, Redwood Shores, CA
Breast Cancer Connections 8 th Annual Breast Cancer Conference, Redwood Shores, CA

Presentations and Articles

- Feb 2015 Speaker at UCSF Breast Oncology Program Scientific Retreat, San Francisco, CA Dec 2013 Co-authored workshop paper on Sixth International Workshop on Breast Density and Breast Cancer Risk Assessment - published in California Breast Cancer Research Program eNews, Vol 7, No 12. Dec 2013
- Dec 2012 Presented Breast Cancer Connections services to Palo Alto Medical Foundation Tumor Board meeting

D. PUBLICATIONS

- "Rapid Testing for Infectious Diseases", 1990 and 1993 proprietary market studies for diagnostics industry
- "Therapeutic Opportunities in the Treatment of Skin Cancers", Bio Industry, Vol. 9, No. 11, October 1992 2.
- "Anatomy of a Financing Window: An Analysis of Biotechnology Public Offerings, January 1991-March 1992",
- Spectrum, Biotechnology Overview, Issue 39, 1992. "Advances in the Treatment of Psoriasis", Drug and Market Development, Vol 2, No 9/10, 1992
- "Lowering the Boom: An Analysis of Biotechnology Public Offerings, January 1992 March 1993", Spectrum,
- Biotechnology Overview, Issue 50, 1993
- "The Role of Viruses in Human Cancer", Bio Industry, Vol. 10, No. 2, February 1993
- "Systemic Mycosis: The Challenge of Opportunistic Infection in the 1990s", Bio Industry, Vol. 10, No. 4, April 1993
- 10. "Biotechnology Bears Down on the Market: An Analysis of Biotechnology Public Offerings, January 1993 June 1994", Spectrum, Pharmaceutical Industry Dynamics, Issue 83, 1994

- 11. "1994 Updates: Timelines to Commercialization for Biomedical Products," *Spectrum, Pharmaceutical Industry Dynamics*, Issue 72, 1994.
- 12. "1995 Updates: Timelines to Commercialization for Biomedical Products," *Spectrum, Pharmaceutical Industry Dynamics*, Issue 103, 1995.
- 13. "Implications of Recent Trends in Biotechnology Financing," Spectrum, Pharmaceutical Industry Dynamics, Issue 113, 1995.
- 14. "1996 Updates: Timelines to Commercialization for Biomedical Products," *Spectrum, Pharmaceutical Industry Dynamics*, Issue 132, 1996.
- 15. "Lessons from the Latest Biotech Product Failures," Spectrum, Pharmaceutical Industry Dynamics, Issue 145, 1997.
- 16. "The EntreMed Phenomenon: Biotech's Wild Ride from Lab to Press to Wall Street and Back," Spectrum,
- 17. Pharmaceutical Industry Dynamics, Issue 7, 1998.
- 18. "1998 Updates: Timelines to Commercialization for Biomedical Products," *Spectrum, Pharmaceutical Industry Dynamics*, Issue 18, 1998.

E. NONPROFIT ORGANIZATIONS

UCSF Breast Oncology Program, San Francisco, CA Member, Breast Science Advocacy Core	2014 - present
Athena Breast Health Network, University of California Advocate Advisor	2014 - present
Susan G. Komen - SF Bay Area Grants Committee member Community Profile Committee member	2014 - present 2014 - present
Harvard Alumni Association, Cambridge, MA Board of Directors (National Schools & Scholarships Committee)	2014 - present
The Harvard Club of Silicon Valley, Palo Alto, CA Chair, Harvard Book Prize Committee Board of Directors Alumna interviewer for College admissions Co-President	2007 - present 2006 - present 2005 - present 2008 - 2009
Bay Area Cancer Connections, Palo Alto, CA Board of Directors (Marketing and Audit Committees) Research Advocacy Program advocate Cancer Buddy (peer mentor)	2010 - 2014 2012 - 2014 2005 - 2014
The Harvard Club of Northwestern Connecticut Alumna interviewer for College admissions	2000 - 2004
The Harvard Club of New York City, NY Schools Subcommittee Chair Alumna interviewer for College admissions	1989 - 2000 1981 - 2004

Vivian Lee

PROFESSIONAL EXPERIENCE

Aqua Partners LLC (New York / Palo Alto) Founder and Managing Director

1983 - Present

Strategic advisory firm focused on life science industry. Broad range of services including opportunity assessment, valuation, portfolio analysis, product positioning, licensing strategy, market research, business development. Mandates successfully completed include:

- formation of Revotar Biopharmaceuticals AG as European spin-off of Texas Biotechnology Corp;
- private financing of Micrus Corp.;
- private financing of Ortec;
- valuation and fairness opinion services on acquisition of Avantec Vascular and LightLab Imaging by Goodman Co.;
- formation of private equity fund management firm Global Biomedical Partners AG;
- valuation assessment and work-out of Restoragen;
- seed fund formation advisory services to Marubeni Corporation

Other strategic advisory services provided to:

Adria Laboratories Merck KGaA (Germany)

Armstrong Pharmaceuticals Myogen
Boehringer-Ingelheim (Germany) Nanosystems

Brigham & Women's Hospital OmniViral Therapeutics

CanBas Co. Ltd (Japan) Pharmajet

Celltech (UK) Pharming BV (Netherlands)

Cell Works (Hong Kong/US)

Samsung Fine Chemicals (Korea)

Creatogen GmbH Scigen Ltd (Singapore)
Cubist Pharmaceuticals Simbiosys Biowares (India)

Devax Systemix
Ferring Pharmaceuticals (Denmark/US) Triage Medical

Genetics Institute Tulane University
Groupe Lipha SA (France) Welsh Development Agency (UK)

Ikonisys Xenova (UK)

Israel Chemicals Ltd. (Israel) Zambon Group SpA (Italy)

Global Biomedical Partners (New York / Zurich) Advisor 2000 – 2003; Venture Partner 2003 – 2005

2000 - 2005

Management of \$100 million Swiss-based life science private equity fund, Biomedicine LP, with investment focus in biopharmaceutical and medical device companies.

Board member of Innodia (acquired by Neurochem) and Board observer of Syntonix Pharmaceuticals (acquired by Biogen Idec). Other portfolio companies include Anadys Pharmaceuticals, Arena Pharmaceuticals, Cytokinetics, Enanta Pharmaceuticals, Exelixis, Genaissance, Memory Pharmaceuticals, Renovis, Sunesis.

Fund made 23 venture capital investments, resulting in exits through 11 IPOs and 2 trade sales. Activities include sourcing and evaluating new investment opportunities, due diligence, structuring and negotiating investment terms, valuation and returns modeling, balancing portfolio, managing divestments of public positions, board service, oversight of portfolio company progress, support of portfolio company management and presentations to investors. Fund was successfully sold and portfolio management responsibilities transitioned to acquirer in 2005.

W.R. Grace & Co. (New York) Business Analyst, Corporate Venture Department

1981 - 1983

Corporate venture arm of \$7 billion Fortune 50 diversified chemical conglomerate. Evaluated new venture investment opportunities in emerging high tech, industrial and agricultural biotechnology fields. Reviewed business plans, financial analysis on business opportunities, reports on overview of industry sub-sectors of interest to Grace's existing operations, including specialty chemicals, advanced materials, separation and filtration systems, cell culture systems.

EDUCATION

Harvard University, A.B. Biochemistry, Cum Laude in General Studies, 1981.

Conducted research in laboratory of Harvey Cantor, Department of Tumor Immunology, Dana Farber Cancer Institute, 1978-1981.

Conducted tumor immunology research in laboratory of Richard Gershon, Department of Pathology. Yale University School of Medicine, 1978 – 1980.

Research assistant in laboratory of Kenneth K. Kidd, Department of Human Genetics, Yale University School of Medicine, 1976 – 1977.

VOLUNTEER

UCSF Breast Oncology Program Member, Breast Science Advocacy Core	2014 - present
Athena Breast Health Network, University of California Advocate Advisor	2014 - present
Susan G. Komen Advocate in Science Community Grant Peer Reviewer - SF Bay Area Community Profile Committee - SF Bay Area	2014 - present 2014 - present 2014 - present
Bay Area Cancer Connections, Palo Alto, CA Patient peer mentor/cancer Buddy Breast cancer research advocate Board of Directors (Marketing and Audit Committees)	2005 - 2014 2012 - 2014 2011 - 2014
Harvard Alumni Association, Cambridge, MA Board of Directors (Schools and Scholarships Committee)	2014 - present
The Harvard Club of Silicon Valley Chair, Harvard Book Prize Co-President Board of Directors Alumna interviewer for college admissions	2007 - present 2008 - 2009 2006 - present 2005 - present
The Harvard Club of New York City Schools Subcommittee Chair Alumna interviewer for college admissions	1989 - 2000 1981 - 2004

PERSONAL

Fluent in French and Mandarin. Married, two children.

SUMMARY

Highly energized professional with strong clinical development and business development background. A self-motivated successful leader and consensus builder, with a positive outlook and extremely successful, strategic problem solving skills.

EXPERIENCE

ARVINAS, INC, New Haven, CT Executive Director, Development

Apr 2015- Present

- Lead cross functional development teams to create and execute strategy for all regulatory activities associated with early phase human clinical trials
- Create virtual development team by identifying and contracting with key external consultants, in order to expand internal capabilities and ensure appropriate oversight of all IND-enabling and development activities
- Management responsibility for oversight of project budgets, deliverables, and timelines
- Assure the quality of all team deliverables
- Negotiate with and influence internal stakeholders; establish relationships with external key opinion leaders
- Provide program-related updates to executive management, Scientific Advisory Board and Board of Directors

ALEXION PHARMACEUTICALS, Cheshire, CT

Director, Quality Risk Management, Development

Apr 2014- Mar 2015

- Partner with Clinical Quality Assurance to develop and institutionalize a Quality Issue
- Management/CAPA process which ensures compliance with global regulations, minimizes development risks and provides a clear understanding of roles and responsibilities for all internal stake holders
- Oversee "root cause analysis" for all CAPAs categorized as critical to the organization
- Trend quality data for early detection of potential quality issues/effectiveness checks for known quality issues
- Identify and mitigate quality-related risk across development functions
- Communicate quality data and metrics to senior leaders
- · Facilitate inspection readiness, provide SME preparation during external audits
- Serve as host to FDA inspector and/or lead "back room" activities during routine regulatory inspections

Director, Project Management & Strategic Drug Development

Oct 2012-Apr 2014

- Lead cross-functional research and development project teams with appropriate prioritization, driving to on-time and on-budget completion of deliverables, across all phases of drug development
- Provide clear direction on strategic product development requirements to meet expectations of external customers and business stakeholders
- Author regulatory documents including pre-IND and pre-filing briefing books, INDs, clinical study reports and Type 2 Variation summary documents (module 2)
- Oversee and facilitate advisory board meetings with key opinion leaders

- Apply creative problem solving skills, as needed
- Interface with senior management on project related issues/updates and formal reporting procedures
- Participate in the assessment of external development opportunities
- Member of R&D "Capabilities" work stream which assessed technology gaps within the organization and made recommendations to the Leadership Team to address same

PIONEER VALLEY LIFE SCIENCES INSTITUTE, Springfield, MA Jan 2010-Sept 2012 Business Development Manager

- Develop and maintain the long-term vision and strategic plan for Institute business development including long-term sustainability initiatives and short-term funding sources. Responsible for presenting these plans to Senior Management and obtaining buy-in/approval from the Board of Directors
- · Drafts business plans for Institute technologies
- Identify new sources of grants and contracts from government and nongovernmental agencies that represent a good fit with Institute's scientific expertise
- Design and implement regional breast disease patient registry, in conjunction with the Director of the Baystate Breast Center
- Prepare and deliver presentations on Institute inventions and intellectual property to potential licensors
- Identify, solidify and manage Institute's strategic partnership with for profit or nonprofit corporations
- Institute representative for state and regional economic development initiatives

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Sept 2011- Oct 2012

Member, Commercial Review Council

• Established in 2007, CPRIT is funded by a \$3B bond from the State of Texas, with the goal of funding ground breaking cancer prevention and research programs and services to benefit the citizens of the state. The Commercial Review Council is comprised of nationally renowned industry and oncology professionals who review investment applications in conjunction with the Scientific Review Council to identify and make funding recommendations for the projects with the best commercial prospects.

MARCIA WOODS CONSULTING

Sept 2003-Jan 2010

- Identify potential oncology candidate molecules for future in-licensing and development, based on client's stated strategic needs
- Analyze data and construct out-licensing summaries/presentations for clients seeking a collaborative development partner for an internal program
- Identify external funding opportunities for key scientific programs
- Provide input into short- and long-term strategic planning for clients
- Facilitate positive interactions and collaborative relationships between clients and potential licensing partners.

BRISTOL-MYERS SQUIBB, Princeton, NJ

Sept 2000-Aug 2003

Director, Oncology/Pharmacogenomics
External Science Technology and Licensing
Corporate Staff

- Coordinated and contributed to the development of successful therapeutic area and pharmacogenomic strategies, including internal pipeline prioritization and external development opportunities
- Member of the Oncology Strategic Therapeutic Area Team, a high level cross functional team which makes strategic recommendations to senior management

regarding Franchise development

- Translate complex scientific and commercial developments into external development opportunities and drive those opportunities forward to successful completion
- Form, lead, and manage cross-functional teams to assess, diagnose, and bring to closure strategic licensing opportunities for the global oncology business
- Lead the strategic development, financial analysis for negotiations of licensing candidates
- Maintain/facilitate relationships with licensors/potential licensors
- Identify third parties with an interest in licensing/collaborating with BMS in the development of BMS Oncology assets and negotiate win-win agreements
- Member of BMS Pharmaceutical Research Institute Task Force on Pharmacogenomics

BRISTOL-MYERS SQUIBB FOUNDATION, New York, NY

Oct 2002- Aug 2003

Member, Oncology Unrestricted Grants Committee

 One of only five Bristol-Myers Squibb employees who worked with oncology experts to award the BMS Foundation's "Unrestricted Oncology Research Grant" and the prestigious "Lifetime Achievement Award".

BRISTOL-MYERS SQUIBB, Princeton, NJ

Feb 2000-Sept 2000

Director, Oncology Global Marketing

- Responsible for the creation and adoption internal "tool kit" to strategically prioritize the development of pipeline products
- Co-Lead of the BMS Pharmaceutical Research Institute Task Force on Pharmacogenomics
 - -Provided business impact scenarios, which assumed varying degrees of technical success for the oncology market
 - -Successfully negotiated with Millennium Pharmaceuticals to develop research and business strategies to apply pharmacogenomic technologies to the development of BMS pipeline products
 - -Communicated potential impact of pharmacogenomics to local BMS oncology business units
- Responsible for the identification and review of potential business development opportunities:
 - Assessed of commercial interest and strategic fit with franchise objectives.
 - Estimated potential sales based on patient populations, cost of good and market share for in-licensing candidates and strategic fit for technology platforms.
 - Presented opportunities to senior management for funding approval prior to the initiation of negotiations by BMS legal experts.
- Member of Licensing Excellence Task Force, initiated at the request of the President of the Pharmaceutical Research Institute whose goal was to optimize workflow and become the preferred alliance partner in the industry.

Awards:

-Two-time recipient of the Pharmaceutical Research Institute President's Award, both given in 2000

Associate Director, New Products Manager, New Products Oncology Global Marketing Nov. 1997- Jan 2000 May 1996-Nov 1997

- Member of 'Oncology 2010' Task Force, which was created to estimate the value of the oncology market and specific market segments in the year 2010 and beyond.
 The Task Force also made near-term strategic recommendations to the President of Worldwide Medicines Group in order to capitalize on future market opportunities.
- Developed and authored BMS' 1997 Global Oncology Long-range Strategic Plan
- Represent worldwide oncology business operations to multi-disciplinary project

development teams.

Actively participate in all matters concerning new oncology product commercialization

BRISTOL-MYERS SQUIBB, Wallingford, CT

Senior Clinical Scientist

Feb 1995-Apr 1996

Clinical Scientist/Associate Clinical Scientist

Feb 1991-Jan 1995

Clinical Cancer Research Department

- Assigned increasing levels of responsibilities as a clinical trials monitor working with both conventional cytotoxic and biologic agents.
- Preparation of annual IND safety updates, final study reports and integrated clinical summaries.
- Clinical representative to multi-disciplinary project teams.
- Trained and mentored new clinical scientists.

Awards:

- Pharmaceutical Research Institute's President's Award, 1993

PAREXEL International Corporation, Cambridge, MA

Team Leader/Clinical Research Associate Clinical Research Associate Jan 1990-Jan 1991 Oct 1989-Jan 1990

- Director of multidisciplinary project teams.
- Monitored Phase I-III clinical trials according to FDA regulations and GCP guidelines.
- Trained junior Clinical Research Associates and ad hoc team members in GCP and disease characteristic information.

EDUCATION

Yale University, School of Medicine, Department of Epidemiology and Public Health, New Haven, CT - Master of Public Health, Chronic and Infectious Disease Epidemiology, 1989.

Bates College, Lewiston, ME - Bachelor of Science, Biological Sciences, 1987.

PUBLICATIONS

- N. Onetto, **M. Dougan**, S. Hellman, N. Gustafson, J. Burroughs, A. Florczyk, R. Canetta, M. Rozencweig, "Safety Profile" in <u>Taxol in Cancer Treatment</u>, W.P. McGuire III and E.K. Rowinsky eds., Marcel-Dekker, 1995, pages 121-14.
- N. Onetto, R. Canetta, B. Winograd, R. Catane, M. Dougan, J. Grechko, J. Burroughs, and M. Rozencweig: Overview of Taxol Safety, Journal of the National Cancer Institute, Workshop on Taxol and TAXUS, Monographs No. 15, 1993.

ABSTRACTS

- BJ Giantonio, TA Gilewski, MA Bookman, L Norton, D Kilpatrick, **MA Dougan**, WJ Slichenmyer, NM Onetto, RM Canetta: A Phase I Study of Weekly BR96-Doxorubicin (BR96-DOX) In Patients With Advanced Carcinoma Expressing the Lewis-Y Antigen, Proceedings of the American Society of Clinical Oncology, No. 1380, pg. 443, May, 1996.
- W.J. Slichenmyer, M.A. Bookman, T.A. Gilewski, J.L. Murray, M.N. Saleh, **M. Dougan**, D. Healey, N. Onetto: Phase I Clinical Trials with the Immunoconjugate BR96-Doxorubicin, Proceedings of the American Chemical Society, 211 Meeting, Pt. 1, CARBO32, 1996.
- N. Onetto, A. LoBuglio, M. Bookman, T. Gilewski, M. Dougan, D. Healey, K.E. Hellstrom, P. Trail, C. Siegall, M. Birkhofer, R. Canetta: Tumor Targeting therapy Directed to LE Y Antigen, EORTC Early Drug Development Meeting, June, 1995.

N. Onetto, M. Rozencweig, R. Canetta, B. Winograd, R. Catane, M. Dougan, J. Grechko, J. Burroughs: An Integrated Analysis of the Safety of Single Agent Taxol, Second National Cancer Institute Workshop on Taxol and TAXUS, Sept. 23-4, 1992.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.

Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Atwal, Gurinder S

eRA COMMONS USER NAME (agency login): ATWALG

POSITION TITLE: Associate Professor

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing,

include postdoctoral training and residency training if applicable.)

	<u> </u>		
INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
	· · · · · · · · · · · · · · · · · · ·		
University of Cambridge	BA	06/1997	Medicine and Physics
University of Cambridge	MA	06/1998	Physics
Offiversity of Cambridge	IVIA	00/1990	Filysics
Cornell University, Ithaca, NY	PHD	08/2002	Physics
Corrich Crity Crafty, Itriaca, 141	טוו ון	00/2002	i ilysics
Princeton University, Princeton, NJ	Postdoctoral Fellow	08/2005	Physics
•			'
Institute for Advanced Study, Princeton, NJ	Postdoctoral Fellow	09/2008	Systems Biology
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A. PERSONAL STATEMENT

I am originally trained in Medicine and Theoretical Physics and in my current position, as Assistant Professor of Quantitative Biology, my stated research interests are in computational cancer biology. My expertise lies in developing novel machine learning methods in handling large-scale computational biology datasets and working in an interdisciplinary environment at the intersection of computation, experimental cancer biology, and the clinic. Much of my cancer-related research is in collaboration with experimental labs here at CSHL, often applying new computational methods to genomic data generated locally. Education of junior researchers has been a strong interest of mine and, to this end, I have developed two new graduate courses and a programing bootcamp, which have been attended by postdoctoral fellows. I am also a member of the Executive Committee of the Watson School for Biological Sciences. I have trained and mentored postdoctoral fellows at CSHL, most recently a fellow with graduate training in theoretical physics and who now runs his own computational biology group in Boston focusing on analyses of cancer sequencing data. I would welcome the opportunity to mentor an NRSA trainee in my lab as a Preceptor of the CSHL Cancer Gene Discovery and Cancer Biology Postdoctoral Research Training Program.

- 1. Atwal GS, Kirchhoff T, Bond EE, Montagna M, Menin C, et al. Altered tumor formation and evolutionary selection of genetic variants in the human MDM4 oncogene. Proc Natl Acad Sci U S A. 2009 Jun 23;106(25):10236-41. PubMed PMID: 19497887; PubMed Central PMCID: PMC2700939.
- 2. Grochola LF, Zeron-Medina J, Repapi E, Finlayson A, Cai Y, et al. p53 in the Clinics. New York: Springer; 2012. The Inheritance of p53
- 3. Ouyang W, Liao W, Luo CT, Yin N, Huse M, et al. Novel Foxo1-dependent transcriptional programs control T(reg) cell function. Nature. 2012 Nov 22;491(7425):554-9. PubMed PMID: <u>23135404</u>; PubMed Central PMCID: <u>PMC3771531</u>.
- 4. Kinney JB, Atwal GS. Equitability, mutual information, and the maximal information coefficient. Proc Natl Acad Sci U S A. 2014 Mar 4;111(9):3354-9. PubMed PMID: <u>24550517</u>; PubMed Central PMCID: <u>PMC3948249</u>.

B. POSITIONS AND HONORS

Positions and Employment

2002 - 2005	Postdoctoral Researcher, Lewis-Sigler Institute for Integrative Genomics
2008 - 2015	Assistant Professor, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY
2008 - 2010	Adjunct Member, Cancer Institute of New Jersey, New Brunswick, NJ
2012 -	Adjunct Assistant Professor, Stony Brook University, Stony Brook
2015 -	Associate Professor, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY

Other Experience and Professional Memberships

Honors

1998	Keighley's Bequest Award , Gonville and Caius College, University of Cambridge
2010	One of the top 25 Rising Young Investigatyors in Systems Biology, Genome Technology
	Magazine
2013	Winship Herr Award for Excellent in Teaching, Watson School for Biology Science, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY

C. Contribution to Science

- 1. I have developed algorithms to detect evidence of molecular natural selection from genome-wide data.
 - a. Atwal GS, Bond GL, Metsuyanim S, Papa M, Friedman E, et al. Haplotype structure and selection of the MDM2 oncogene in humans. Proc Natl Acad Sci U S A. 2007 Mar 13;104(11):4524-9. PubMed PMID: 17360557; PubMed Central PMCID: PMC1838634.
 - b. Atwal GS, Kirchhoff T, Bond EE, Montagna M, Menin C, et al. Altered tumor formation and evolutionary selection of genetic variants in the human MDM4 oncogene. Proc Natl Acad Sci U S A. 2009 Jun 23;106(25):10236-41. PubMed PMID: 19497887; PubMed Central PMCID: PMC2700939.
 - c. Mizuno H, Atwal G, Wang H, Levine AJ, Vazquez A. Fine-scale detection of population-specific linkage disequilibrium using haplotype entropy in the human genome. BMC Genet. 2010 Apr 23;11:27. PubMed PMID: 20416085; PubMed Central PMCID: PMC2873552.
- 2. Candidate genes in the TP53 tumor suppressor pathway that we inferred to be under natural selection, have been shown to be associated with estrogen-driven tumors and fertility in mice and humans.
 - a. Hu W, Feng Z, Atwal GS, Levine AJ. p53: a new player in reproduction. Cell Cycle. 2008 Apr 1;7(7):848-52. PubMed PMID: 18414047.
 - b. Kang HJ, Feng Z, Sun Y, Atwal G, Murphy ME, et al. Single-nucleotide polymorphisms in the p53 pathway regulate fertility in humans. Proc Natl Acad Sci U S A. 2009 Jun 16;106(24):9761-6. PubMed PMID: 19470478; PubMed Central PMCID: PMC2700980.
 - c. Mehta MS, Vazquez A, Kulkarni DA, Kerrigan JE, Atwal G, et al. Polymorphic variants in TSC1 and TSC2 and their association with breast cancer phenotypes. Breast Cancer Res Treat. 2011 Feb;125(3):861-8. PubMed PMID: 20658316; PubMed Central PMCID: PMC3876413.
 - d. Grochola LF, Zeron-Medina J, Repapi E, Finlayson A, Cai Y, et al. p53 in the Clinics. New York: Springer; 2012. The Inheritance of p53
- 3. I have pioneered methods in the theory and development of information theory in the analysis of biological datasets.

 - b. Atwal GS, Rabadán R, Lozano G, Strong LC, Ruijs MW, et al. An information-theoretic analysis of genetics, gender and age in cancer patients. PLoS One. 2008 Apr 9;3(4):e1951. PubMed PMID: 18398474; PubMed Central PMCID: PMC2276689.
 - c. Kinney JB, Atwal GS. Equitability, mutual information, and the maximal information coefficient. Proc Natl Acad Sci U S A. 2014 Mar 4;111(9):3354-9. PubMed PMID: <u>24550517</u>; PubMed Central PMCID: <u>PMC3948249</u>.
 - d. Kinney JB, Atwal GS. Parametric inference in the large data limit using maximally informative models. Neural Comput. 2014 Apr;26(4):637-53. PubMed PMID: <u>24479782</u>.
- 4. I have pioneered computational methods to analyze whole genome data in tumors such as copy number variants and ChIP-Seq data.
 - a. Chen M, Pratt CP, Zeeman ME, Schultz N, Taylor BS, et al. Identification of PHLPP1 as a tumor suppressor reveals the role of feedback activation in PTEN-mutant prostate cancer progression. Cancer Cell. 2011 Aug 16;20(2):173-86. PubMed PMID: <u>21840483</u>; PubMed Central PMCID: <u>PMC3176728</u>.

 Ouyang W, Liao W, Luo CT, Yin N, Huse M, et al. Novel Foxo1-dependent transcriptional programs control T(reg) cell function. Nature. 2012 Nov 22;491(7425):554-9. PubMed PMID: <u>23135404</u>; PubMed Central PMCID: <u>PMC3771531</u>.

D. RESEARCH SUPPORT

Ongoing Research Support

2015/07/30-2019/06/30

5R01CA137050-06A1, NIH

Lloyd Trotman (PI)

Mechanisms and treatment of PTEN mutant prostate tumorigenesis

This grant supports generation and analysis of mouse models for the validation of candidate genes of human prostate cancer progression and its treatment.

Role: Co-Investigator

2014/01/01-2015/12/31

17-A723, STARR

Greg Hannon (PI)

Functional analysis of ectopic germline gene expression in cancer

The goal of this project is to develop algorithms to elucidate the genomic landscape of ectopic expression of germline genes in glioblastoma.

Role: CPI

2008/09/01-2015/08/31

125217, QB Simons

Michael Wigler (PI)

Simons Foundation Center for Quantitative Biology

The goal of this project is to formulate mathematical models to understand the role of population genetics in informing human disease

Role: Faculty

Completed Research Support

2009/08/01-2012/07/31

13-A123, STARR

Li (PI)

Genome Wide Mapping of Fox01 Binding-Sites in vivo and functional study of Fox02 Target genes in mouse T lymphocutes

The goal of this project is to develop algorithms for the study of Fox01 target genes in mouse T lymphocytes

Role: Co-PI

2005/08/15-2011/07/31

5P30CA45508-23, CSHL Cancer Center Support Grant

Bruce Stillman (PI)

CSHL Cancer Center Support Grant

The goal of this project is to further understand the haplotype distribution within the p53 network.

Role: Project PI



First Quarter 2016 Audit Subcommittee Status Report

Weaver has executed the internal audit plan for FY 2015 that was previously approved by CPRIT management and presented to the Audit Subcommittee.

2015 Internal Audit Plan and Status

Internal Audit	Description
Risk Assessment	The internal audit risk assessment was conducted with CPRIT management August 28, 2015. The risk ratings assigned to the significant processes of CPRIT were reviewed and finalized with Management resulting in a risk rated internal audit universe. The completed risk assessment was utilized to develop a three-year internal audit plan. The Internal Audit Risk Assessment Report and Proposed 3-Year Internal Audit Plan was issued October 16, 2015.
Grants Management	Fieldwork for the Grants Management audit was completed on July 27, 2015. We issued the report on August 26, 2015. The audit resulted in an overall assessment of "Satisfactory" with nine total findings. Eight findings are risk rated as Moderate, and one is rated as Low. Follow-up procedures on the remediation of the findings are included in the proposed audit plan for fiscal year 2016.
Expenditures	Fieldwork for the Expenditures audit was completed on August, 24, 2015. We issued the report on October 7, 2015. The audit resulted in an overall assessment of "Strong" with two total findings. Both findings are risk rated as Low.
Follow-ups of Information Technology and Governance	Fieldwork for the Governance and Information Technology follow-up procedures was completed August 14, 2015. We issued a combined report on both follow-ups on September 14, 2015. The audit resulted in an overall assessment of "Satisfactory" with two total findings related to Information Technology. One finding is rated as Moderate; the other is rated as Low. We identified no findings related to Governance.
	We performed follow-up procedures over prior internal audit findings for CPRIT grant recipients. Fieldwork of the follow-up procedures was completed July 31, 2015. We issued the report on August 31, 2015. The following grantees and their associated assessment is indicated below:
Grantee Field Audits	Texas A&M University Health Science Center – Satisfactory University of Texas – Strong University of Texas Southwestern Medical Center – Satisfactory University of Texas Health Science Center – Houston – Unsatisfactory Texas Nurses Foundation – Strong
	Texas A&M University Health Science Center and University of Texas Southwestern Medical Center each had one finding rated as Low. The University of Texas Health Science Center - Houston had one finding rated as High. The other recipients had no findings.



Project Management and Annual Report

Project management and reporting to the Audit Subcommittee and Oversight Committee are ongoing. We completed a draft of the required Annual Report and provided it to management on October 28, 2015. We will work with management to post the report to the CPRIT website by the required deadline.

Proposed 3-Year Internal Audit Plan

Based on the results of the risk assessment and discussions with management, we have developed a Proposed 3-Year Internal Audit Plan for the consideration of the Audit Subcommittee (attached). The internal audit plan for fiscal year 2016 includes Internal Audits over four process areas and Follow-up Procedures over findings identified in two of the fiscal year 2015 Internal Audits. We request the Audit Subcommittee approve the fiscal year 2016 Internal Audit Plan.

No additional matters have come to Internal Audit's attention.

Alyssa G. Martin, CPA, MBA, Internal Auditor

Executive Partner

Weaver and Tidwell L.L.P.

Alyx Spitm



CPRIT Proposed 3-Year Internal Audit Plan

Audit Area	Risk Rating	Summary Procedures	Audit Focus
		2016 Planned New Internal Audits	
Information Security	HOH	Internal Audit will include an evaluation of risks and internal controls in place related to CPRITs Information Security practices. Activities to be evaluated will include Internal and External Security, Logical Access, Physical Access, Risk Assessment, and Compliance with security and privacy requirements.	Internal Audit
Commodity and Service Contracts	#g#	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Commodity and Service Contracts practices. Activities to be evaluated will include Contract Compliance, Contract Management and Professional Services.	Internal Audit
Revenue	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRITs Revenue practices. Activities to be evaluated will include General Obligation Bonds, License Plate Fees, Application Fees, Revenue Sharing and Other Revenue Sources.	Internal Audit
Cash Management	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRITs Cash Management practices. Activities to be evaluated will include Electronic Funds Transfer Processing, State Treasury Reconciliations and Cash Forecasting.	Internal Audit
		2016 Planned Internal Audit Follow-up	
Pre-Award Grant Management Post-Award Grant Management Grant Contracting	uline	Internal Audit will perform follow-up procedures on 2015 Internal Audit findings to ensure corrective action has been taken.	Follow-up
Information Technology Services	Moderate	Internal Audit will perform follow-up procedures on 2015 Internal Audit findings to ensure corrective action has been taken.	Follow-up
		2016 Planned Annual Requirements	
Project Management	A A	Track overall internal audit procedures, coordinate audit activities, and reporting to management.	Project Management
Update Risk Assessment	NA	Perform required annual update of risk assessment.	Policy Compliance
Annual and Quarterly Board Reports	NA V	Prepare and submit required Annual Internal Audit Report and quarterly reports to the Audit Subcommittee and Oversight Committee of internal audit activities.	Policy Compliance



CPRIT Proposed 3-Year Internal Audit Plan

Audit Area	Risk Rating	Summary Procedures	Project Type
		2017 Planned New Internal Audits	
Procurement	Ē	Internal Audit will include an evaluation of risks and internal controls in place related to the CPRITs Procurement practices. Activities to be evaluated will include Purchase Orders, Bidding and Awards, Contract Negotiation and Approval, Vendor Management and Selection, Vendor Acceptance, and Vendor Set-up.	Internal Audit
Non-Grant Expenditures	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRITs Non-Grant Expenditures process. Activities to be evaluated will include Vendor Invoice Review, Approval and Recording, Vendor Payments, Vendor Monitoring, Travel and Expense Reimbursement, and Independent Contractors.	Internal Audit
Training	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRITs Training practices. Employee Technical Training, Oversight Committee Training, Employee Compliance and Ethics Training, and Grantee Training and Onboarding.	Internal Audit
External Affairs	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRITs External Affairs practices. Activities to be evaluated will include Governmental Affairs and Public Information processing.	Internal Audit
		2017 Planned Internal Audit Follow-up	
Information Security	High	Internal Audit will perform follow-up procedures on 2016 Internal Audit findings to ensure corrective action has been taken.	Follow-up
Commodity and Service Contracts	Hgh	Internal Audit will perform follow-up procedures on 2016 Internal Audit findings to ensure corrective action has been taken.	Follow-up
Revenue	Moderate	Internal Audit will perform follow-up procedures on 2016 Internal Audit findings to ensure corrective action has been taken.	Follow-up
Cash Management	Moderate	Internal Audit will perform follow-up procedures on 2016 Internal Audit findings to ensure corrective action has been taken.	Follow-up
		2017 Planned Annual Requirements	
Project Management	N A	Track overall internal audit procedures, coordinate audit activities, and reporting to management.	Project Management
Update Risk Assessment	Ą	Perform required annual update of risk assessment.	Policy Compliance
Annual and Quarterly Board Reports	¥	Prepare and submit required Annual Internal Audit Report and quarterly reports to the Audit Subcommittee and Oversight Committee of internal audit activities.	Policy Compliance



CPRIT Proposed 3-Year Internal Audit Plan

Audit Area	Risk	Summary Procedures	Project Type
		2018 Planned New Internal Audits	
Pre Award Grant Management	HADIN	Internal Audit will include an evaluation of risks and internal controls in place related to CPRITs Grants	
Post Award Grant Monitoring	High	Management, Monitoring and Contracting practices. Activities to be evaluated will include RFA Review Process, Conflicts of Interest, Peer Review, Grant Application Approval, Contract Terms, Fund Availability, Certifications, Grant Contract Execution, Grantee Monitoring, Sub-Contractor Monitoring, Granto, Donardia	Internal Audit
Grant Contracting	Moderate	and Scientific Review.	
Information Technology Services	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRITs Information Technology practices. Activities to be evaluated will include Network Operations, Help Desk, Change Management, Website Maintenance, Intranet Content Management, Third-Party Services, Disaster Recovery and Business Continuity Planning.	Internal Audit
Budget and Planning	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRITs Budgeting and Planning practices. Activities to be evaluated will include Budgeting, Forecasting and Planning, Agency Strategic Plan, Budget Review and Amendment, Capital Expenditures, and Budget Monitoring.	Internal Audit
		2018 Planned Internal Audit Follow-up	
Procurement	地址	Internal Audit will perform follow-up procedures on 2017 Internal Audit findings to ensure corrective action has been taken.	Follow-up
Non-Grant Expenditures	Moderate	Internal Audit will perform follow-up procedures on 2017 Internal Audit findings to ensure corrective action has been taken.	Follow-up
Training	Moderate	Internal Audit will perform follow-up procedures on 2017 Internal Audit findings to ensure corrective action has been taken.	Follow-up
External Affairs	Moderate	Internal Audit will perform follow-up procedures on 2017 Internal Audit findings to ensure corrective action has been taken.	Follow-up
		2018 Planned Annual Requirements	
Project Management	NA	Track overall internal audit procedures, coordinate audit activities, and reporting to management.	Project Management
Update Risk Assessment	NA A	Perform required annual update of risk assessment	Policy Compliance
Annual and Quarterly Board Reports	N A	Prepare and submit required Annual Internal Audit Report and quarterly reports to the Audit Subcommittee and Oversight Committee of internal audit activities.	Policy Compliance

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

IA # 01-15 - INTERNAL AUDIT REPORT OVER GRANT MANAGEMENT

REPORT DATE: JULY 27, 2015

ISSUED: AUGUST 26, 2015

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The Oversight Committee
Cancer Prevention and Research Institute of Texas
1701 North Congress Avenue, Suite 6-127
Austin, Texas 78701

This report presents the results of the internal audit procedures performed for the Cancer Prevention and Research Institute of Texas (the Institute) during the period June 15, 2015 through July 27, 2015 relating to the Institute's grant management process.

The objectives of this internal audit were to evaluate the design and effectiveness of CPRIT's grant management processes. The objectives were organized as follows:

- A. Verify that internal controls over Grants Management are designed to ensure the effective management of the process and address all key risks.
- B. Ensure that the controls in place over high-risk processes are operating effectively.

To accomplish these objectives, we conducted interviews with personnel responsible for grant management. We also reviewed documentation and performed specific testing procedures to assess controls. Procedures were performed at the Cancer Prevention and Research Institute of Texas Service Center offices and were completed on July 15, 2015.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

Weaver and Siduell, L.L.P.

Austin, Texas August 26, 2015

ISSUED: AUGUST 26, 2015

BACKGROUND

The Cancer Prevention and Research Institute of Texas (CPRIT or the agency) was established with the goal to expedite innovation in cancer research and product development, and to enhance access to evidence-based prevention programs throughout the State of Texas. To accomplish these goals, CPRIT awards grants for a wide variety of cancer-related research and the delivery of cancer prevention programs and services by public and private entities located in Texas. All CPRIT-funded research will be conducted in state by Texas-based scientists and reflect CPRIT's mission to attract and expand the state's research capabilities and create high quality new jobs in Texas.

Under the guidance of its governing body, the Oversight Committee, CPRIT develops and publishes requests for applications from organizations to solicit their research or development projects for funding. CPRIT reviews those applications and awards grant funds. Throughout the application and grant award processes, applicants and the personnel responsible for evaluating applicants and making grant award recommendations must disclose any conflicts of interest.

After the Oversight Committee approves grant award recommendations, contracts are negotiated and executed with the grant applicants who were awarded funds. Once contracts are executed, CPRIT oversees the performance of grantees through reporting and monitoring mechanisms. Grantees are responsible for providing CPRIT with financial and programmatic reports in order to receive the grant funds as a reimbursement of expended funds.

CPRIT also performs monitoring of the grant recipients through a monitoring program. This program is based on a risk assessment of all the organizations who receive grant funds from the agency. Based upon the risk assessment, desk or field monitoring procedures are performed to evaluate the grantees compliance with the financial and programmatic requirements of the contract and to validate the research and prevention program progress reported in the periodic reports submitted to CPRIT.

Funding for a grant is completed when the term of a contract expires, or when a grantee has expended the total funded award amount. CPRIT monitors each grant award through the life of the grant contract and validates the completion of the required compliance and financial reports before providing the grantee with their final reimbursement and closing out the grant.

AUDIT OBJECTIVE AND SCOPE

The audit focused on the Grants Management processes in place at the Cancer Prevention and Research Institute of Texas (CPRIT). We reviewed the procedures for appropriate risk and regulatory coverage and compliance. Key functions and sub-processes within the Grants Management process that were reviewed include:

- Grant Acceptance and Allocation
- Request for Applications (RFAs)
- Awarding Grant Funds
- Contract Execution
- Contract Compliance
- Financial Reporting
- Grantee Reporting
- Compliance Monitoring
- Contract Extension
- Contract Closeout
- Grant Funding Closeout



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The audit did not include direct monitoring of grant recipients or an evaluation of the future state of procedures and controls. The focus of our evaluation was on reoccurring procedures that were in place throughout the coverage period and are anticipated to remain in place in the future.

Our procedures were designed to ensure relevant risks are covered and verified the following:

Grant Acceptance and Allocation

Grant allocations are in compliance with State requirements

Request for Applications (RFAs)

- RFAs are reviewed for compliance with State requirements
- RFA solicitations are approved prior to issuance

Awarding Grant Funds

- Potential conflicts of interest are reported by individuals making grant award decisions and appropriate steps are taken to recuse reviewers with conflicts during the pre-award process
- Peer review is adequately performed on awards
- Applications are solicited and processed for appropriate qualifications and resources that meet Administrative Review requirements
- Awards are processed for eligible, qualified recipients based on Peer Review, Program Integration Committee, and Oversight Committee approval
- Proposed grant awards are reconciled to available funds to ensure that budget is available for the proposed grants prior to final approval

Contract Execution

- Award commitments/contracts are appropriately authorized by the Oversight Committee
- Use of standard contract templates are appropriate and approved
- Deviations to standard and required contract terms are appropriate and approved
- Contracts clearly define compliance requirements and include State requirements
- Contract renewals are validated via the RFA process
- Required certifications are reviewed and approved prior to contract execution
- Contract amendments and revisions are appropriately reviewed and approved

Contract Compliance

- State grant laws and regulations are met
- Arrangements allowing self-dealing or kickback payments are not in place
- Conflicts of interest by the grantee have been identified and reported
- Contract records are adequately documented and retained

Financial Reporting

- Reimbursement requests are reviewed and approved
- Costs charged to CPRIT grants are monitored by CPRIT personnel
- Grant distributions are approved prior to disbursement
- Periodic grant financial monitoring procedures regarding budgets, coding, and fixed assets are performed
- Use of matching funds is reviewed and validated for completeness and accuracy
- Financial reports and audits from grantees are reviewed and potential irregularities and exceptions are investigated



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Grantee Reporting

- Reports submitted by grantees to CPRIT are monitored for completeness, accuracy and timeliness
- Programmatic/scientific assessments of progress reports are conducted with results accepted
- Reports are reviewed for compliance with contract terms
- Cost analysis of program progress is performed on grantee reported results

Compliance Monitoring

- Grantees receive onboarding and periodic compliance and management training
- Costs charged to CPRIT grants are monitored by CPRIT personnel
- Use of matching funds is reviewed and validated for completeness and accuracy
- Grantee policies and procedures are reviewed by CPRIT
- Grantee accounting systems are reviewed for sufficiency by CPRIT
- Grantee segregation of duties is assessed
- Grantee procurement practices are reviewed to ensure appropriate use of CPRIT funds
- Grantees have appropriate controls and monitoring of inventory purchased with grant funds
- Agreements with subcontractors include all CPRIT contractual requirements and administrative regulations
- Grantees have procedures in place to monitor subcontractors for compliance
- Corrective action follow-up performed for grantees and subcontractor with deficiencies

Contract Extension

- Grantee financial and programmatic performance is evaluated prior to extensions
- Extensions are reviewed and approved

Contract Closeout

- Services and fund expenditures are verified prior to closeout
- All open requests for reimbursement are validated and reconciled
- Grant and grantee documents are archived and retained
- Final grantee progress report evaluations are performed

Grant Funding Closeout

- Final progress reports are verified prior to contract close-out
- Grant funds are reconciled by funding sources prior to close-out
- Close-out final payments are approved

The objectives of this internal audit were as follows:

- A. Verify that internal controls over Grants Management are designed to ensure the effective management of the process and address all key risks.
- B. Ensure that the controls in place over high-risk processes are operating effectively.

Our procedures included interviewing key personnel within the Legal, Compliance, and Operations groups to gain an understanding of the current processes in place, examining existing documentation, evaluating the internal controls over the process, and testing the effectiveness of the controls in place. We evaluated the existing policies, procedures and processes in their current state. The coverage period of the internal audit was from June 1, 2014 through May 31, 2015.



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EXECUTIVE SUMMARY

Through our interviews, evaluation of internal control design and testing of transactions we identified nine findings. The listing of findings include those items that have been identified and are considered to be non-compliance issues with documented CPRIT policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover significant risks to CPRIT. These issues could have significant financial or operational implications.

A summary of our results, by audit objective, is provided in the table below. See the Appendix for an overview of the Assessment and Risk Ratings.

OVERALL ASSESSMENT	SATISFACTORY

SCOPE AREA	RESULT	RATING
Objective A: Verify that internal controls over Grants Management are designed to ensure the effective management of the process and address all key risks.	We identified 50 controls to be in place in the process, 40 of which were determined to be critical to the internal control structure and are defined as "key" controls. There are opportunities to improve the process and control environment, including: Review of Financial Status Reports Grantee onboarding and compliance training Subcontractor compliance monitoring Grant close-out	SATISFACTORY
Objective B: Ensure that the controls in place over high-risk processes are operating effectively.	Controls in place were generally operating as designed. We identified the following opportunities for improvement: Review of supporting documentation for Financial Status Reports Follow-up of prior grantee findings Complete reporting by grantees Timely submission of requests for no cost extensions Obtaining reports prior to final grant payments	SATISFACTORY

Other opportunities for improvement were identified through our interviews, evaluation of internal control design and transactional testing. These observations include those items that are not considered to be non-compliance issues with documented agency policies and procedures. These are considered process improvement observations and the intent for the recommendations are to strengthen current agency processes and controls. These observations were provided to management separately.

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CONCLUSION

Based on our evaluation, the Grant Management function has procedures and controls in place to conduct effective management of the significant processes within CPRIT. However, we identified several opportunities to improve the processes and effectiveness of the controls within the Grant Management process.

CPRIT should standardize the procedures for reviewing Financial Status Reports submitted by grantees, including the expectations and requirements of the documentation to support expenditures of grantees. CPRIT should also ensure that grantees have submitted all the required reports prior to releasing the funds related to reimbursement requests. Additionally, CPRIT should add the review of subcontractor compliance, perform follow-up procedures on grantees with prior audit findings, and provide onboarding training to their grant recipients as part of their grant compliance program.

We recommend that CPRIT implement additional formalized procedures over Grant Management and strengthen the control weaknesses identified. Internal Audit will conduct follow-up procedures to validate remediation efforts in Fiscal Year 2016.



DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

ISSUED: AUGUST 26, 2015

DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

Our procedures included interviewing key personnel within the Legal, Compliance, and Operations groups to gain an understanding of the current processes in place, examining existing documentation, evaluating the internal controls over the process, and testing the effectiveness of the controls in place. We evaluated the existing policies, procedures and processes in their current state.

Objective A: Design of Internal Controls

Verify that internal controls over Grants Management are designed to ensure the effective management of the process and address all key risks.

- 1. Procedures Performed: We gained an understanding of the current grant management processes by conducting interviews with key personnel; reviewing existing procedures, standardized forms and documents used by CPRIT's personnel; and assessing CPRIT's administrative rules to identify key controls. We examined the following sub-processes:
 - Grant Acceptance and Allocation
 - Request for Applications (RFAs)
 - Awarding Grant Funds
 - Contract Execution
 - Contract Compliance
 - Financial Reporting
 - Grantee Reporting
 - Compliance Monitoring
 - Contract Extension
 - Contract Closeout
 - Grant Funding Closeout

We evaluated the controls identified against expected controls to determine whether the identified reoccurring grant monitoring procedures and internal controls are sufficiently designed to mitigate the critical risks associated with the Grants Management process. We identified any unacceptable risk exposures due to gaps in the existing control structure as well as opportunities to strengthen the effectiveness and efficiency of the existing procedures.

Results: We identified 50 controls in place over the significant activities within the grant management function. We identified five findings where improvements in the processes, polices, and procedures can be made.

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Significant Process	Key	Non-Key Controls	Total Controls	Control Gaps
Grant Acceptance and Allocation	2	0	2	
Request for Applications (RFAs)	2	0	2	
Awarding Grant Funds	15*	2	17*	Finding 2
Contract Execution	7*	0	7*	
Contract Compliance	7*	1*	8*	
Financial Reporting	5*	3	8*	
Grantee Reporting	2	0	2	
Compliance Monitoring	4	2	6	Finding 1 Finding 3
Contract Extension	1	1	2	
Contract Closeout	4*	2	6*	
Funding Closeout	4*	2*	6*	Finding 4
Total	53*	13*	66*	4

^{*}The actual key control count totals 40 "key" controls, 10 non-key controls, and 50 total controls. The totals displayed the table above represents where certain controls address risks in multiple processes. The mapping above presents the coverage of controls throughout the significant grant management processes to demonstrate the mitigation of risks by the control structure in place.

Finding 1 – MODERATE – Review of Financial Status Reports (FSR): CPRIT Grant Accountants have inconsistent standards by which FSRs are reviewed. The inconsistencies relate to determining the sufficiency of the supporting documentation provided by the grantee. For example, some Grant Accountants require third-party supporting documentation such as an invoice to be provided for expenses above \$1,000 while others have a more stringent threshold for the same requirement. In addition, CPRIT does not have a formal timeframe for completion of the FSR review. Grant Accountants are instructed to complete the review as soon as possible. A formal deadline by which Grant Accountants must complete the review has not been established.

Recommendation: CPRIT should implement a standardized FSR review process to ensure that all grantees are treated equally. Detailed descriptions of requirements regarding the supporting documentation should be included in CPRIT's policies and procedures. In addition, CPRIT should establish a "no later than" deadline by which FSR review should be completed and include that information in its policies and procedures.

CPRIT Management Response: CPRIT management agrees that Grant Accountants should use consistent standards to determine there is sufficient documentation to support expenditures in FSRs. The requirement that Grant Accountants apply consistent standards in the review of FSRs has been verbally communicated to them. The agency has also implemented a requirement that Grant Accountants complete FSR reviews within 30 days from the date of FSR submission. The Financial Reports section of CPRIT's Administrative Policies and Procedures is being updated to formally address these requirements. CPRIT is revising the grant Policies and Procedures Guide to incorporate the standards that FSR submissions must meet to be in compliance. In the meantime, CPRIT sent notification of these requirements to grantees through the CARS-CPRIT Grants Management System in July 2015.

Responsible Party: Chief Operating Officer, Deputy Executive Officer and General Counsel Implementation Date: November 1, 2015

ISSUED: AUGUST 26, 2015

Finding 2 – MODERATE – Grantee Onboarding and Training: CPRIT does not provide any onboarding training to grantees. CPRIT's General Counsel, Chief Compliance Officer and Grant Specialist Manager provide compliance training to grantees on a periodic basis (several times per year). This training is not mandatory for all grantees to attend.

Recommendation: CPRIT should implement a mandatory onboarding and compliance training for all grantees.

CPRIT Management Response: CPRIT management agrees that onboarding and periodic compliance training for all grantees should be mandatory. An onboarding and grantee training project is currently underway and staff resources have been allocated for this purpose. These trainings may cover administrative rule requirements, reporting requirements, CGMS overview, and compliance program overview, and will be phased in as CPRIT makes necessary administrative rule changes.

Responsible Party: Chief Compliance Officer Implementation Date: December 31, 2015

Finding 3 – MODERATE- Subcontractor Monitoring: Grantees are responsible for ensuring that CPRIT's contractual requirements and administrative regulations are followed by their subcontractor. Grantees accept this responsibility by executing the grant contract. However, CPRIT has no process in place to verify that contractual requirements and administrative regulations are followed by a grantee's subcontractor. Indirect costs and invoices from subcontractor are reviewed by Grant Accountants as part of the Financial Statement Report review, but they are not treated differently than other vendor invoices.

Recommendation: CPRIT should add a review of subcontractor compliance as a part of desk and onsite reviews of grantees. This review should include identifying subcontractor, assessing subcontractor agreements for inclusion of required elements, and reviewing a sample of subcontractor payments for allowability and appropriateness.

CPRIT Management Response: CPRIT management agrees that grantee desk and onsite reviews should include a review of subcontractor compliance. Monitoring reviews will be revised to include specific protocols to identify subcontractors, assess subcontractor agreements for inclusion of flow-through provisions, and review a sample of subcontractor expenditures for allowability and appropriateness.

Responsible Party: Chief Compliance Officer Implementation Date: September 30, 2015

Finding 4 - MODERATE - Grant Close-Out: During the audit period, CPRIT considered a grant to be closed and eligible for final payment when a grantee submits their final Financial Status Report (FSR) and Progress Report. However, a grantee may still have been delinquent in submitting other required reports, such as an Inventory Report or Historically Underutilized Business Report. Consequently, CPRIT did not have a mechanism to enforce the submission of all required reports until it began holding final payments until all reports were submitted. CPRIT is in the process of modifying the business rules in the CPRIT Grants Management System (CGMS) to increase the period of time before the system automatically closes a grant, preventing the submission of other required reports.

Recommendation: CPRIT should continue updating its close-out process to ensure that all required documentation is submitted prior to final payment. CPRIT should also consider modifying CMGS to prevent grants from being closed out without all the required reports being included in the file.

ISSUED: AUGUST 26, 2015

CPRIT Management Response: CPRIT management agrees that all required grant documentation should be complete before making a final payment on and closing a grant. CPRIT will develop a grant contract compliance checklist for grant closeout to document that the final payment can be made on a grant moving through the closeout process. The CPRIT Application Receipt System's post-award Grants Management System (CARS-CGMS) was modified on May 11, 2015, eliminating the business rule that automatically closed grants in the CARS-CGMS system six months after the contract end date. By eliminating this business rule, CPRIT staff with Contract Manager roles in the CARS-CGMS system will manually close a grant record after they have verified that a grantee has submitted all required reports.

Responsible Party: Deputy Executive Officer and General Counsel, Chief Operating Officer,

Operations Manager

Implementation Date: September 30, 2015

2. Procedures Performed: We verified whether controls have been implemented to address prior internal audit findings. We prepared a schedule of prior findings and compared the controls identified as part of the process evaluation to the schedule of findings to determine prior findings had been adequately addressed.

Results: No findings identified.

Objective B: Effectiveness of Controls

Ensure that the controls in place over high-risk processes are operating effectively.

- 1. Procedures Performed: We selected a sample of 46 new grant awards during the scope period of June 1, 2014 May 31, 2015. For each award, we obtained the evidence and verified the following:
 - Administrative review was performed
 - Peer review was performed and grantee score justified advancement
 - Review Council review was performed
 - Program Integration Committee Review was performed
 - CEO Affidavit was completed for the award
 - Oversight Committee approved the award
 - If a Product Development/Commercialization Grant, Due Diligence and Intellectual Property reviews were performed
 - Application Pedigree was completed for the grantee
 - Conflict of interest certifications were completed by PIC Members and OC members.
 - Conflict of interest certifications were completed by Peer Reviewers.
 - Availability of funds was verified prior to award.

Results: No findings identified.



ISSUED: AUGUST 26, 2015

- 2. Procedures Performed: We selected a sample of 50 new grant contracts executed during the scope period of June 1, 2014 May 31, 2015 and verified the following:
 - Authorization by the Oversight Committee
 - Evidence of contract execution by all required parties (CEO and grantee Authorized Signing Official ASO)
 - Evidence that required certifications were provided: Matching Funds, Payment of Taxes,
 Suspension and Debarment, Drug-Free Workplace, and Tobacco Free Workplace
 - Evidence of approval of any contract Amendments
 - Acknowledgement of reporting requirements
 - Evidence of agreement of Intellectual Property and Revenue Sharing requirements
 - Evidence grantee was not funded prior to execution of all contract documents.

Results: No findings identified.

- 3. **Procedures Performed:** We selected a sample of 70 Financial Status Reports submitted during the scope period of June 1, 2014 May 31, 2015 and verified the following:
 - Review of costs for allowability by CPRIT personnel
 - Sufficiency of supporting documentation to justify costs charged
 - Mathematical validation of the reimbursement request by CPRIT employees
 - Reports were submitted timely (within 90 calendar days of the end of the state fiscal quarter)

Results: We identified that the Financial Status Reports selected for testing were reviewed by CPRIT personnel to ensure that costs included in the reports were allowable, that the requests were validated for mathematical accuracy and that reports were submitted by grantees in a timely manner. We also identified that all but one of the selected reports had sufficient supporting documentation.

Finding 5 - MODERATE – Salary Supporting Documentation: For one of 70 grant disbursements reviewed, we determined that the grantee did not provide sufficient support for its Financial Status Report reimbursement request. No employees were listed on the grantee's Personnel Level of Effort submitted with the report, but the grantee claimed reimbursement of salary expenses. The payment was made in June 2014 and CPRIT subsequently began requiring additional supporting documentation for salary and benefit expenses in July 2014.

Recommendation: CPRIT should formally update its FSR review procedures to include the requirement to review the Personnel Level of Effort and ensure that all Grant Accountants and Grant Specialists perform this process as part of their reviews. As of August 2014, CPRIT informally modified its FSR review process to include comparing the names of the employees paid to the Personnel Level of Effort (LOE) submitted by the grantee to ensure that the salary and benefit payments requested for reimbursement were paid to appropriate individuals.

CPRIT Management Response: CPRIT management agrees that Grant Accountants should use consistent standards to determine there is sufficient documentation to support expenditures such as salary expenses in FSRs. The Financial Reports section of the CPRIT's Administrative Policies and Procedures are being updated to formally address these requirements. CPRIT is revising the grant Policies and Procedures Guide to incorporate the expense documentation requirements for FSR submissions from grantees.

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Responsible Party: Deputy Executive Officer and General Counsel, Chief Operating Officer,

Operations Manager

Implementation Date: November 1, 2015

- **4. Procedures Performed:** We selected all grants that have received either a desk or onsite review during the scope time period of June 1, 2014 May 31, 2015 and verified the following:
 - · Review was performed timely and completely
 - · The use of matching funds was validated by CPRIT
 - Grantee policies, accounting systems, segregation of duties, procurement, inventory management, and subcontractor monitoring procedures are reviewed by CPRIT

Results: No findings identified.

5. Procedures Performed: We selected all grants that were previously monitored by Internal Audit or CPRIT Grant Specialists and verified whether CPRIT performed follow-up procedures related to the corrective actions.

Results: We determined that follow-up procedures were not consistently executed to verify grantees remediated prior findings.

Finding 6 - MODERATE - No Follow-up of Prior Grantee Monitoring Findings: Twelve of the prior 13 corrective actions recommended as a result of prior internal audit monitoring of grantees did not have evidence of follow-up by CPRIT to validate corrective action had been implemented by grantees.

Recommendation: CPRIT should assign each unresolved finding to a process owner and have routine updates to track the resolution of all remaining findings. The current status of each outstanding finding should be communicated to the Oversight Committee with a plan on how to resolve the finding and what items are still pending. At a minimum, prior findings should be addressed during the Grant Monitoring process.

CPRIT Management Response: CPRIT management agrees that grantee audit findings should be resolved. As part of its work as CPRIT's contracted internal auditor in fiscal year 2015, Weaver and Tidwell performed follow-up procedures on prior outstanding audit findings of grantee monitoring audits and concluded that all of the prior findings have been remediated. During fiscal year 2015, CPRIT transitioned the grant monitoring responsibility from Internal Audit to the Compliance Program under the oversight of the Chief Compliance Officer. The Compliance Program has incorporated grant monitoring findings in the risk assessment used to develop and adjust CPRIT's annual monitoring plan and will conduct follow-up procedures on future grant monitoring findings to ensure they are addressed.

Responsible Party: Chief Compliance Officer Implementation Date: September 30, 2015

- **6. Procedures Performed:** We selected a sample of 70 grants that had expenditure reimbursement during the scope period of June 1, 2014 May 31, 2015 and verified the following:
 - All grantees submitted their required reports and matching fund certificates.
 - Required reports and matching fund certificate were reviewed by CPRIT
 - Grantees were monitored for contract and legal compliance requirements
 - Allegations of fraud, waste, abuse and noncompliance were investigated and/or resolved timely
 - CPRIT's required annual reports were reviewed prior to submission and were submitted timely
 - Annual Progress Reports were submitted timely and reviewed by CPRIT
 - Quarterly Progress Reports related to cancer prevention grants were reviewed by CPRIT
 - Funds were only disbursed to grantees without delinquent reports

Results: During the audit period, CPRIT implemented a multi-phase reconciliation program to ensure that all required reports were submitted by grantees. As a result of the reconciliation, 32 of the 70 grantees in our sample were identified to have outstanding reports. Across the 32 grantees, 61 of the 544 required financial and progress reports due were outstanding past their due date. One of the past due reports was an Annual Progress Report.

Of the 32 grantees, payments to nine of the grantees were put on hold. However payments were released to the other 23 grantees.

Finding 7 - MODERATE - Incomplete Grantee Reporting: Of the 70 grants tested, funds were distributed to 23 grantees who had reports outstanding and due to CPRIT.

Recommendation: CPRIT should implement a payment release checklist that includes a listing of reports that are required to be submitted by the grantee. The Contract Manager should complete the checklist, verifying the receipt of all required reports, and provide it to the agency accountant to review as part of the documentation for the payment release process.

CPRIT Management Response: CPRIT management agrees that all required grant documentation should be complete before making a payment on a grant. CPRIT will develop a grant contract compliance checklist to document that a reimbursement payment can be released for each grant.

Responsible Party: Deputy Executive Officer and General Counsel, Chief Operating Officer, Operations Manager

Implementation Date: September 30, 2015

- 7. **Procedures Performed:** We selected a sample of 72 grant contracts that received an Amendment F No Cost Extension during the scope period of June 1, 2014 May 31, 2015 and verified the following:
 - Grantee was current with financial reporting (FSRs) prior to the extension
 - Grantee was current with Progress Reports prior to the extension
 - Extension was reviewed and approved by the CPRIT CEO
 - Extension did not allocate any additional funds to the grantee
 - Extension was requested between 180 and 30 days prior to contract expiration

Results: For the 72 contract extensions selected for testing, we identified that the grantees who requested extensions were current in filing their FSR and Progress reports and that no additional funds were allocated to the grantees. We also identified that the extensions were appropriately

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reviewed and approved. However, we identified one of the selected extensions was requested within 30 days of the contract expiration.

Finding 8 - LOW - No Cost Extensions: We determined that one out of 72 contract extensions from the period was requested outside the allowed timeframe of 30-180 days from the contract's end date. This no cost extension was requested on June 27, 2014, just 3 days prior to contract expiration date of June 30, 2014. The request for extension received final approval on July 29, 2014. CPRIT adopted an administrative rule effective January 2014 outlining the submission timeline. However, CPRIT did not implement a business rule in CGMS to enforce the timeline until June 27, 2014.

Recommendation: CPRIT should adhere to the no cost contract extension requirements outlined in the Chapter 703 of the Texas Administrative Code. CPRIT should not approve requests for contract extension that are not made between 180 and 30 days prior to the contract expiration date. The implementation of the business rule in the CGMS in June 2014 should enforce this requirement.

CPRIT Management Response: CPRIT management agrees that CPRIT should adhere to the no cost contract extension requirements in Chapter 703 of the Texas Administrative Code. However, the administrative rules lack a process for accommodating exceptional or extenuating circumstances that delay the extension request. CPRIT will implement a process where the CEO may approve no cost extensions not made between 180 and 30 days prior to the contract expiration date. The CEO will publicly report such approvals to the Oversight Committee. CPRIT's administrative rules will be amended to reflect the process for CEO approval of exceptional or extenuating circumstances.

Responsible Party: Deputy Executive Officer and General Counsel, Operations Manager Implementation Date: March 1, 2016

- **8. Procedures Performed:** We selected all grant contracts with an end date between June 1, 2014 and May 31, 2015, and verified the following:
 - Final Financial Status Reports (FSRs) was submitted and reviewed timely
 - Final Progress Report was submitted and reviewed timely
 - Outstanding invoices or payment claims were reconciled prior to payment
 - Final reconciliation was performed to identify any unexpected funds to be returned to CPRIT

Results: For the 42 grants that had a contract termination date between June 1, 2014 and May 31, 2015, we identified that the FSRs and Final Progress Reports were submitted and reviewed timely and that the final reconciliations were performed to identify any unexpected funds to be returned to CPRIT. However, we also identified that five of the 42 grants had at least one required report outstanding, but still received their final payment.

Finding 9 - MODERATE – Grant Close-Out Payments: We determined that for five of 42 grants tested during the period with a termination date between June 1, 2014 and May, 31, 2015, CPRIT processed payment of the Final Financial Status Report while at least one required report from the grantee was outstanding. Four of the five grants were missing at least one required Financial Report, and one of the five did not have a Final Progress Report prior to final payment.

Recommendation: CPRIT should continue updating its close-out process to ensure that all required documentation is provided prior to final payment. Additionally, the final process for close-out should be formally documented in CPRIT's policies and procedures.

ISSUED: AUGUST 26, 2015

CPRIT Management Response: CPRIT management agrees that CPRIT should update its close-out process to ensure all required documentation is provided prior to final payment. CPRIT will develop a grant contract compliance checklist to document that a final payment can be released for each grant. CPRIT will describe the final close out process set forth in CPRIT's administrative rules, T.A.C. 703.14(d), in the administrative policies and procedures.

Responsible Party: Deputy Executive Officer and General Counsel, Chief Operating Officer,

Operations Manager

Implementation Date: November 1, 2015

APPENDIX

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS IA# 01-15 GRANTS MANAGEMENT JULY 27, 2015

ISSUED: AUGUST 26, 2015

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

REPORT RATINGS

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
 - Reliability and integrity of financial and operational information
 - Effectiveness and efficiency of operations and programs
 - o Safeguarding of assets
 - o Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.

The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.



The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

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RISK RATINGS

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

Worderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the agency or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the organization
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

IA # 02-15 - INTERNAL AUDIT FOLLOW UP PROCEDURES REPORT OVER PRIOR YEAR GOVERNANCE AND INFORMATION TECHNOLOGY FINDINGS

REPORT DATE: AUGUST 14, 2015

ISSUED: SEPTEMBER 14, 2015

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The Oversight Committee
Cancer Prevention & Research Institute of Texas
1701 North Congress Avenue, Suite 6-127
Austin, Texas 78701

This report presents the results of the internal audit follow up procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT or the Institute) during the period July 27, 2015 through August 14, 2015 related to the findings from the 2014 Internal Audit Reports over CPRIT Governance and Information Technology, dated June 19, 2014 and July 25, 2014, respectively.

The objective of these follow up procedures was to validate that adequate corrective action has been taken in order to remediate the issues identified in the prior year Internal Audit Reports over CPRIT Governance and Information Technology.

To accomplish this objective, we conducted interviews with key personnel responsible for CPRIT Governance and Information Technology. We also reviewed documentation and performed specific testing procedures to validate actions taken. Procedures were performed at the Cancer Prevention & Research Institute of Texas office and were completed on August 14, 2015.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

Weaver and Siduell, L.S.P.

WEAVER AND TIDWELL, L.L.P. Austin, Texas September 14, 2015

ISSUED: SEPTEMBER 14, 2015

BACKGROUND

In 2014, internal audits over the Institute's governance processes and information technology processes were completed and reported to the Oversight Committee. The internal audit report over the CPRIT's governance structure and activities identified four areas for improvement related to policies, procedures and overall training and awareness of the Oversight Committee.

The internal audit report over information technology (IT) processes identified five areas for improvement related to policies, procedures, the annual risk assessment, security administration and the updating of the disaster recovery and business continuity plan.

The 2015 Internal Audit Plan included performing procedures to validate that CPRIT management has taken steps to address the internal audit findings.

FOLLOW-UP OBJECTIVE AND SCOPE

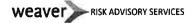
The follow up procedures focused on the remediation efforts taken by CPRIT management to address the findings included in the 2014 CPRIT Governance and Information Technology Internal Audit Reports, and to validate that appropriate corrective action had been taken. We reviewed each report and identified the following findings:

CPRIT Governance

- The Oversight Committee was in the process of gaining an understanding of the Institute's strategic plan and improving CPRIT's strategic direction through the program priority setting process.
- 2. The Institute's Policies and Procedures Guide had not been updated since 2009 and did not incorporate the changes made to the Texas Administrative Code.
- 3. The Oversight Committee was not consistently provided with meeting materials with sufficient time to review prior to their meetings. Additionally, the Oversight Committee was not fully aware of Grantee activity.
- 4. The Oversight Committee was not fully aware of requirements and constraints regarding appropriate communication in accordance with the Texas Administrative Code and Open Meetings Act. Additionally, the Oversight Committee was still forming subcommittees and establishing a regular meeting schedule.

Information Technology

- 1. The IT policies and procedures had been updated as required by the Texas Administrative Code (TAC 202); however, 14 of the 27 policy documents were awaiting Management review and communication to employees.
- 2. The IT risk assessment had not been completed. Additionally, remediation of IT vulnerabilities identified in third-party penetration tests had been performed; however, no reports had been prepared evidencing the mitigation of the risks identified by the scans.
- There had been no reviews of systems and networks user accounts and the individual rights for each
- 4. The Disaster Recovery Plan and Business Continuity Plan were not up to date.
- 5. Backup tapes had not been rotated to a secure off-site facility.



ISSUED: SEPTEMBER 14, 2015

Our procedures included interviewing key personnel within the Legal, Operations and IT groups in order to gain an understanding of the corrective actions taken to address the findings in the respective report, reviewing policies and procedures, obtaining related documentation and/or performing observations and testing to ensure that policies and procedures are appropriately implemented.

EXECUTIVE SUMMARY

Through our interviews, review of documentation, observations and testing we identified 2 findings. The list of findings includes those items that have been identified and are considered to be non-compliance issues with CPRIT policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover significant risks to CPRIT. These issues could have significant financial or operational implications.

A summary of our results, by area, is provided in the table below. See the Appendix for an overview of the Assessment and Risk Ratings.

OVERA	LL ASSESSMENT	SATISFACTORY
SCOPE AREA	RESULT	RATING
Governance: Validate that appropriate corrective action has been taken in order to adequately remediate the findings identified in the Internal Audit Report dated June 19, 2014	We identified that the four findings identified in the 2014 CPRIT Governance Internal Audit Report have been remediated by CPRIT management.	STRONG
Information Technology: Validate that appropriate corrective action has been taken in order to adequately remediate the findings identified in the Internal Audit Report dated July 25, 2014	We identified that remediation efforts have been made for all five findings from the 2014 Information Technology Internal Audit Report. However, two of the findings were only partially remediated. The two findings that were partially remediated relate to: Completing an IT risk assessment to meet all the requirements in TAC 202 Including systems administered and hosted by third parties in the annual user access review	SATISFACTORY

ISSUED: SEPTEMBER 14, 2015

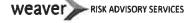
CONCLUSION

Based on our evaluation, CPRIT management has made efforts to remediate the findings from the 2014 internal audit reports. However, continued efforts need to be made to fully remediate findings from the Information Technology Internal Audit.

In order to completely remediate the Information Technology Internal Audit, CPRIT should continue to refine the IT risk assessment process to include all relevant systems and applications, including applications and systems hosted and administered by third parties. The risk assessment process should also include documentation of CPRIT's inherent risk profile and a detailed risk response plan.

Additionally, CPRIT should include all applications and systems hosted and administered by third parties in the annual application access review in order to evaluate access rights to all CPRIT data.

We recommend that CPRIT continue to remediate the IT finding and strengthen the existing processes. Internal Audit will conduct follow-up procedures to validate remediation efforts in Fiscal Year 2016.



DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

ISSUED: SEPTEMBER 14, 2015

DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

CPRIT Governance

Our procedures included interviewing key personnel within the Legal and Operations groups to gain an understanding of the corrective actions taken in order to address the findings identified in the 2014 CPRIT Governance Internal Audit Report as well as examining existing documentation and communications and performing testing in order to validate those corrective actions. We evaluated the existing policies, procedures and processes in their current state.

FY 14 Finding 1: Strategic Direction and Oversight - The Oversight Committee was in the process of gaining an understanding of the Institute's strategic plan and improving CPRIT's strategic direction through the program priority setting process.

Procedures Performed: We interviewed personnel in the Legal and Operations groups and learned that the Program Priority Project was presented to the Oversight Committee and approved during the November 19, 2014, Oversight Committee meeting. We reviewed the Program Priority Project documentation and determined that the Oversight Committee had established priorities for the three grant programs: Research Program, Prevention Program and Product Development Program.

Results: Finding remediated.

FY 14 Finding 2: Policies and Procedures Guide - The Institute's Policies and Procedures Guide had not been updated since 2009 and did not incorporate the changes made to the Texas Administrative Code.

Procedures Performed: We obtained and reviewed a draft of the updated GPRIT Grant Policies and Procedures Guide. This draft of the updated policies and procedures is currently in the process of being reviewed and approved by CPRIT management. We obtained the draft and verified that it meets the Texas Administrative Act Section 2001.004 requiring state agencies to "Adopt rules of practice and index rules, orders and decisions." Furthermore, we verified that the Guide includes an updated policy stating that it is to be reviewed and updated at least annually.

Results: Finding remediated.

FY 14 Finding 3: Oversight Committee Materials - The Oversight Committee was not consistently provided with meeting materials with sufficient time to review prior to their meetings. Additionally, the Oversight Committee was not fully aware of Grantee activity.

Procedures Performed: We selected a sample of two of the five Oversight Committee meetings and six of 24 Subcommittee meetings from November 1, 2014 through June 30, 2015. We identified that Oversight Committee materials were made available to the members of the Oversight Committee at least one week in advance of the meeting, and Subcommittee meeting materials were made available to the respective subcommittee between three and seven days in advance of their meeting. The Meeting materials were provided either as attachments to the meeting notification emails or were posted to the Sharepoint Data room, which is available to all members. Additionally, we identified that Officer's Reports were included in the meeting materials provided to the Oversight Committee. These reports discuss items such as grant award recommendations and budget adjustments of grantees.

Results: Finding remediated.



ISSUED: SEPTEMBER 14, 2015

FY 14 Finding 4: Oversight Committee Training - The Oversight Committee was not fully aware of requirements and constraints regarding appropriate communication in accordance with the Texas Administrative Code and Open Meetings Act. Additionally, the Oversight Committee was still forming subcommittees and establishing a regular meeting schedule.

Procedures Performed: We interviewed personnel from the Legal group and obtained a memo prepared by the General Counsel providing training and guidance to the Oversight Committee on the Open Meetings Act. We determined that the guidance was sufficient to inform the Oversight Committee of the requirements per the Open Meetings Act. Additionally, we identified that Subcommittees were formed and regular meeting schedules were established.

Results: Finding remediated.

Information Technology

Our procedures included interviewing key personnel within the Information Technology and Operations groups to gain an understanding of the corrective actions taken in order to address the findings identified in the 2014 Information Technology Internal Audit Report as well as examining existing documentation and communications in order to validate those corrective actions. We evaluated the existing policies, procedures and processes in their current state.

FY 14 Finding 1: Review and Approval of IT Policies - The IT policies and procedures had been updated as required by the Texas Administrative Code (TAC 202); however, 14 of the 27 policy documents were awaiting Management review and communication to employees.

Procedures Performed: We obtained all IT policies and verified that the policies have been approved by CPRIT Management. Additionally, we verified that all current employees have completed IT Security Awareness and Policy Training and have acknowledged receipt of all the policies included on the Institute's SharePoint site.

Results: Finding remediated.

FY 14 Finding 2: IT Risk Assessment - The IT risk assessment compliant with TAC 202 had not been completed. Additionally, remediation of IT vulnerabilities identified in third-party penetration tests had been performed; however, no reports had been prepared evidencing the mitigation of the risks identified by the scans.

Procedures Performed: We obtained the risk assessment performed by CPRIT using Texas' Department of Information Resources' (DIR) Governance, Risk and Compliance tool, Archer. We reviewed the completed IT Self-Assessment Questionnaires for networks, applications and organizational security. Additionally, we obtained the Remediation Report in response to the penetration testing and verified that management addressed the issues identified in the report.

Results: Finding partially remediated. We identified that CPRIT used DIR's IT risk assessment tool to complete IT Self-Assessment questionnaires for the applications and systems administered by CPRIT personnel. However, the risk assessment did not include completed questionnaires for the CARS/CGMS application, which is administered by SRA International. The IT risk assessment also did not include documentation of the determination of which NIST risk questionnaire type to complete (High, Medium, or Low risk), or a risk response plan. We identified that CPRIT's Information Technology Manager prepared the Information Technology Remediation Report that responded to the findings from the penetration test conducted by DIR.

ISSUED: SEPTEMBER 14, 2015

Finding 01 – MODERATE – The IT risk assessment was started with the completion of the DIR administered IT Self-Assessment Questionnaires. However, the IT risk assessment did not include:

- 1) Identification and assessment of all individually significant IT systems (including hosted applications such as CARS/CGMS)
- 2) Documentation of the determination of inherent risk
- 3) Risk response plan detailing the acceptance, transference or mitigation of risks

Recommendation: CPRIT should include all significant applications, including applications hosted by a third party, in the annual IT Risk Assessment. Additionally, the IT Risk Assessment should include documentation on how CPRIT determines and defines the inherent risk of the agency and the risk response plan detailing the acceptance, transference or mitigation of risk for each application and system included in the risk assessment.

CPRIT Management Response: CPRIT management agrees that it should include all significant third-party applications in the annual IT Risk Assessment, documenting the determination of the inherent risk rating and the risk response plan. During this audit cycle, the agency underwent significant changes to its information technology infrastructure, including a major migration to cloud-based provider systems and services for many core functions. In this same period, the Department of Information Resources revised Texas Administrative Code, Sec. 202.24, requiring state agencies to incorporate third-party hosted systems in the IT risk assessment in the same manner as internal agency resources. The agency will work with its vendors to develop a delivery schedule for standard attestation and security certifications (e.g., SOC 1, SSAE16, SAS 70, etc.) so that complete risk assessments can be performed on all systems utilized by the agency. Due to the complexity of some systems, CPRIT may engage a third-party vendor to assist with the evaluation of the risks of those systems and development of the risk response plan.

Responsible Party: Chief Operating Officer, Information Technology Manager

Implementation Date: July 31, 2016

FY 14 Finding 3: User Access Reviews – There had been no formal reviews of systems and network user accounts and the individual rights for each user, and no resulting reports were produced.

Procedures Performed: We obtained evidence of CPRIT's access review performed by the Information Technology Manager and Systems Administrator. We reviewed the access review documentation to ensure that all systems and applications that are utilized by and contain CPRIT data were included in the access review.

Results: Finding partially remediated. The access review included a review of physical access to onsite IT hardware and logical access to CPRIT's network resources, administrative access to servers and applications, and administrator access to third-party applications and systems administered by CPRIT. However, the access review did not include access permissions to applications and systems that are not administered by CPRIT, such as CARS/CGMS.

Finding 02 – LOW – CARS/CGMS was not included in the annual access review. The Operations Manager sends all access requests for each CPRIT employee, as needed, to SRA International who sets up the user account within CARS/CGMS. However, there is no periodic review of access to CARS/CGMS to ensure that access rights are valid.

Recommendation: CPRIT should include CARS/CGMS as part of their annual review of access to their applications and systems, verify appropriate access, and take the necessary corrective action to address any inappropriate access identified.

ISSUED: SEPTEMBER 14, 2015

CPRIT Management Response: CPRIT management agrees that CARS/CGMS should be included in the agency's annual review of access to applications and systems. CPRIT will change its internal process to require that all requests for access including additions, removals, and role changes to the CARS/CGMS application hosted by SRA International are submitted through the existing IT ticketing system so that CPRIT access requests will be formally documented and can be verified against access records from CARS/CGMS. CPRIT's Information Technology Manager will work with SRA International to perform security reviews of the CARS/CGMS application, documenting the results and any necessary remediation efforts if there are findings.

Responsible Party: Chief Operating Officer, Information Technology Manager, Operations Manager

Implementation Date: December 1, 2015

FY 14 Finding 4: Business Continuity Plan - The Disaster Recovery Plan and Business Continuity Plan were not up to date.

Procedures Performed: We interviewed key personnel in the IT group and obtained the updated Business Continuity Plan draft, which includes emergency management and information technology. We reviewed the draft Business Continuity plan to ensure that it was up to date based on our understanding of the current IT environment.

Results: Finding remediated.

FY 14 Finding 5: Relocation of Backup Tapes - Backup tapes were not rotated offsite to a secure facility.

Procedures Performed: We interviewed key personnel in the IT group and identified that CPRIT has migrated to a cloud-based backup system. We also identified that all existing backup tapes have been relocated to the Texas State Library. We also examined records from the Texas State Library documenting the receipt of CPRIT backup tapes to validate that the tapes were moved to a secure offsite facility.

Results: Finding remediated.



APPENDIX

ISSUED: SEPTEMBER 14, 2015

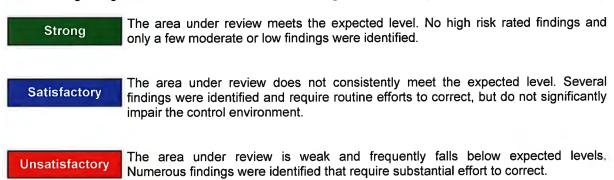
The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

REPORT RATINGS

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- · Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
 - o Reliability and integrity of financial and operational information
 - o Effectiveness and efficiency of operations and programs
 - Safeguarding of assets
 - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:





ISSUED: SEPTEMBER 14, 2015

RISK RATINGS

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the Institute or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the organization
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

IA # 03-15 – INTERNAL AUDIT FOLLOW UP PROCEDURES REPORT OVER PRIOR YEAR GRANTEE MONITORING AUDIT FINDINGS

REPORT DATE: JULY 31, 2015

ISSUED: AUGUST 31, 2015

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The Oversight Committee
Cancer Prevention & Research Institute of Texas
1701 North Congress Avenue, Suite 6-127
Austin, Texas 78701

This report presents the results of the internal audit follow up procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT or the Institute) during the period July 13, 2015 through July 31, 2015 related to the findings from CPRIT's 2014 Grantee Internal Audit Plan. The Grantee Internal Audit Plan included audits to monitor the grant compliance of the following grantees: Texas A&M University Health Science Center, University of Texas Southwestern Medical Center, University of Texas Health Science Center-Houston, University of Texas Austin, and the Texas Nurses Foundation.

The objective of these follow up procedures were to evaluate the design and effectiveness of the corrective action taken by the grantees in order to remediate the issues identified in their respective 2014 Internal Audit Report.

To accomplish this objective, we conducted interviews with key personnel at each grantee who are responsible for CPRIT grant administration and expenditures. We also reviewed documentation and performed specific testing procedures to validate actions taken. Procedures were performed at the individual grantee offices and were completed on August 31, 2015.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

WEAVER AND TIDWELL, L.L.P.

Weaver and Tituell L. L.P.

Austin, Texas August 31, 2015

JULY 31, 2015 ISSUED: AUGUST 31, 2015

BACKGROUND

In 2014, internal audits of selected grantees were performed to monitor grant administration and expenditures of each grantee. These internal audits were completed and reported to the Oversight Committee. The internal audits identified six areas for improvement across the grantees related to: cutoff of reimbursement claims, accurate allocation of expenses, maintenance of reimbursement claims and supporting documentation, allowability of expenses claimed for reimbursement, classification of expenses claimed for reimbursement and accurate and tracking of inventory and equipment.

CPRIT's 2015 Internal Audit Plan included performing procedures to validate that grantee management has taken steps to address their prior year internal audit findings.

FOLLOW-UP OBJECTIVE AND SCOPE

The follow up procedures focused on the remediation efforts taken by each grantee's management to address the findings included in the corresponding 2014 CPRIT Grantee Internal Audit Report, and to validate that appropriate corrective action had been taken. We reviewed each report and identified the following findings:

Texas A&M University Health Science Center (TAMU Health Science Center)

- 1. Incorrect classification of expenditures
- 2. Cutoff of expenditures in Financial Status Reports
- 3. Unallowable expenditures
- 4. Consistency of expenditure classification

University of Texas Southwestern Medical Center (UT Southwestern)

1. Cutoff of expenditures in Financial Status Reports

University of Texas Health Science Center-Houston (UTHSC Houston)

1. Cutoff of expenditures in Financial Status Reports

University of Texas at Austin (UT Austin)

- 1. Inconsistent expenditure classification
- 2. Improper tracking of inventory and equipment

Texas Nurses Foundation

- 1. Subjective allocation of employee time
- 2. Reimbursement claims for payroll and benefits maintained separately
- 3. Lack of documentation to substantiate allocation of expenditures
- 4. Unallowable marketing expenditures
- 5. Unallowable IT expenditures
- 6. Incorrect classification of expenditures



ISSUED: AUGUST 31, 2015

Our procedures included interviewing key personnel at each grantee who are responsible for the administration and expenditures of their respective grants to gain an understanding of the corrective actions taken to address the findings in the respective prior year reports, reviewing policies and procedures, obtaining related documentation and/or performing observations and testing to ensure that corrective actions have been appropriately implemented.

EXECUTIVE SUMMARY

Through our interviews, review of documentation, observations and testing we identified the findings below. The list of findings includes those items that have been identified and are considered to be non-compliance issues with CPRIT grants administration policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover significant risks to CPRIT. These issues could have significant financial or operational implications.

A summary of our results, by area, is provided in the table below. See the Appendix for an overview of the Assessment and Risk Ratings.

OVERALL ASSESSMENT

OVERN	EL AGGEGGIVIENT	BATIOLAGION
Grantee	RESULT	RATING
TAMU Health Science Center: Validate that appropriate corrective action has been taken in order to adequately remediate the findings identified in the Internal Audit Report dated July 25, 2014	We identified that remediation efforts have been made by TX A&M HSC for all four of the prior internal audit findings. However, we identified that the one finding related to cutoff of expenditures in the Financial Status Reports was only partially remediated.	SATISFACTORY
UT Southwestern: Validate that appropriate corrective action has been taken in order to adequately remediate the findings identified in the Internal Audit Report dated August 28, 2014	We identified that remediation efforts have been made by UTSW for the one prior internal audit finding. However, we identified that the one finding related to cutoff of expenditures on the Financial Status Reports from 2014 was only partially remediated.	SATISFACTORY
UTHSC-Houston: Validate that appropriate corrective action has been taken in order to adequately remediate the findings identified in the Internal Audit Report dated July 16, 2014	We identified that no remediation efforts have been made by UTHSC-Houston for the one prior internal audit finding. Financial Status Reports submitted by UTHSC Houston have expenditures that are not reported in the proper period based on CPRIT requirements.	UNSATISFACTORY



SATISFACTORY

ISSUED: AUGUST 31, 2015

UT -Austin: Validate that appropriate corrective action has been taken in order to adequately remediate the findings identified in the Internal Audit Report dated July 24, 2014	We identified that the two findings from the 2014 Grantee Audit Report have been remediated by UT Austin management.	STRONG
Texas Nurses Foundation: Validate that appropriate corrective action has been taken in order to adequately remediate the findings identified in the Internal Audit Report dated June 27, 2014	We identified that the six findings from the 2014 grantee Audit Report have been remediated by Texas Nurses Foundation management.	STRONG

CONCLUSION

Based on our evaluation, management at each grantee, with the exception of University of Texas Health Science Center-Houston, has made efforts to remediate the findings from the 2014 Internal Audit Reports. The Texas Nurses Foundation and UT Austin were determined to have fully remediated their prior year findings. However, we identified that UT Southwestern and TMU Health Science Center each have one finding, related to expense cutoff, which is only partially remediated. The University of Texas Health Science Center Houston did not make any efforts to remediate the 2014 internal audit findings.

As part of their grant monitoring program, CPRIT should continue to perform follow-up procedures and field audits of the UTHSC Houston to ensure that they are in compliance with grant requirements. Additionally, CPRIT should continue to work with UT Southwestern, and Texas A&M Health Science Center to fully remediate the prior year findings.

DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

ISSUED: AUGUST 31, 2015

DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

Texas A&M University Health Science Center

Our procedures included interviewing key personnel within the Sponsored Research Services Department of Texas A&M University Health Science Center to gain an understanding of the corrective actions taken in order to address the findings identified in their 2014 CPRIT Internal Audit Report, as well as examining existing documentation and performing testing in order to validate those corrective actions. We evaluated the existing policies, procedures and processes in their current state.

We performed our procedures over the one active grant for TAMU Health Science Center, RR110532-P2.

FY 14 Finding 1: Incorrect Classification of Expenditures – One expense totaling \$1,650 was incorrectly categorized.

Procedures Performed: We interviewed the personnel responsible for grant administration and expenditures to gain an understanding of the policies and procedures implemented to ensure expenditures are correctly classified. We also selected a sample of 50 expenditure transactions and 14 payroll transactions that were included in Financial Status Reports (FSRs) for the period of August 2014 through June 2015. We obtained and reviewed supporting documentation for each of the selected expenditures to verify that the transactions were properly classified.

Results: Finding remediated.

FY 14 Finding 2: Cutoff of Reimbursement Claims – Fifteen transactions totaling \$98,436 were claimed in the subsequent FSR period after the correct FSR reimbursement dates.

Procedures Performed: We interviewed the personnel responsible for grant administration and expenditures to gain an understanding of the policies and procedures implemented to ensure proper cutoff of expense reimbursement claims requested in FSRs. We selected four FSR reporting periods from August 2014 through June 2015 and examined the payment dates for a sample of 20 transactions requested in those four periods to verify that the payments were requested in the correct FSR period.

Results: We identified that TAMU Health Science Center has implemented a reconciliation process to ensure that expenditures are requested in the correct FSR reporting period. We identified that the reconciliations for each of the four reporting periods selected were completed prior to the submission of the FSR to CPRIT. However, we determined that one of the expenditures examined was not included in the proper FSR reporting period.

Finding 01 – **LOW** – We determined that 1 out of 20 tested expenditures tested was paid by the grantee after the end of the FSR period on which the expense was included. CPRIT policies and procedures dictate that reimbursement claims should not be made until the period in which the funds are disbursed. There were no issues identified with the reconciliation process.

Recommendation: Management should consider revising and/or reiterating policies and procedures to personnel responsible for preparing and reviewing the FSR reconciliations to ensure the proper cutoff of expenditures included in FSRs.

ISSUED: AUGUST 31, 2015

Management Response: Since Institutions of Higher Education in the State of Texas are required to use accrual accounting, a reconciliation process must be performed when preparing every FSR since CPRIT requires reporting on a cash basis rather than an accrual basis. There were 39 reconciling payments that were correctly withheld from the referenced FSR. One payment of \$19.10 was overlooked during the reconciliation process.

The Business Objects report used to identify expenditures for the FSRs has been updated to include the Check Date, in addition to the Transaction Date, so that check dates outside the reporting period can be identified. An Intermediate Accountant (most senior position in functional area) either prepares or reviews all CPRIT FSRs before submission.

Responsible Party: Diane Hassel

Implementation Date: September 1, 2015

FY 14 Finding 3: Unallowable Expenditures – A reimbursement was made for \$5.29 for an unallowable penalty payment, and the associated indirect cost of \$0.28 was also claimed

Procedures Performed: We interviewed the personnel responsible for grant administration and expenditures to gain an understanding of the policies and procedures implemented to ensure that reimbursement requests are submitted only for allowable expenditures. We also selected a sample of 50 expenditure transactions that were included in an FSR for the period of August 2014 through June 2015. We obtained and reviewed supporting documentation for each expenditure to verify that costs requested for reimbursement were allowable.

Results: Finding remediated.

FY 14 Finding 4: Consistency of Expenditure Classification – Several inconsistencies such as incorrect account descriptions in the system, cost share amounts due to an incorrect calculation formula, and missing expenditures used for matching funds were not included in the original matching funds documentation provided.

Procedures Performed: We interviewed the personnel responsible for grant administration and expenditures to gain an understanding of the policies and procedures implemented to ensure that expenditures are consistently classified. We also selected a sample of 50 expenditure transactions that were included in an FSR for the period of August 2014 through June 2015. We obtained and reviewed supporting documentation for each of the selected expenditures to verify that the transactions were properly and consistently classified.

Results: Finding remediated.

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University of Texas Southwestern Medical Center

Our procedures included interviewing key personnel within the Sponsored Program Administration Department of University of Texas Southwestern Medical Center to gain an understanding of the corrective actions taken in order to address the findings identified in their 2014 CPRIT Internal Audit Report, as well as examining existing documentation and performing testing in order to validate those corrective actions. We evaluated the existing policies, procedures, and processes in their current state.

We selected a sample of 11 active grants over which to perform our procedures: R1008, R1109, R1121, R1222, R1225, PP120097, PP120229, RP120613, RP120718-P1, RP120718-P2, and RP120732-P1.

FY 14 Finding 1: Cutoff of Reimbursement Claims – Several of the sampled expenses had either:

- 1) Not yet been paid by UT Southwestern Medical Center (1 transaction totaling \$2,304.09)
- 2) Claimed after the allowed reporting period (50 transactions totaling \$544,634.70), or
- 3) Claimed prior to the reporting period (12 transactions totaling \$24,856.95)

Procedures Performed: We interviewed the personnel responsible for grant administration and expenditures to gain an understanding of the policies and procedures implemented to ensure proper cutoff of expense reimbursement claims requested in FSRs. We selected a sample of 50 transactions across the 11 sampled grants for the period of September 2014 through June 2015, and obtained supporting documentation for each expenditure. We verified that the costs requested for reimbursement related to a valid expense, ensured that it was requested in the correct period and ensured that it was paid by the grantee during the period covered by the FSR.

Results: We determined that one of the 50 expenditures selected was not included in the correct period. The FSR that included the expenditure had not been reviewed, accepted, and paid by CPRIT. Subsequent to the audit, the FSR was revised and re-submitted to CPRIT without the incorrect expenditure.

Finding 1 – LOW – We identified one instance where a \$659.40 transaction requested for reimbursement was not paid by the grantee until after the end of the reporting period covered by the FSR. CPRIT policies and procedures dictate that reimbursement claims should not be made until the period in which the funds are disbursed.

Recommendation: Management should implement and/or improve control activities to ensure that expenses are included in the appropriate FSR, in accordance with CPRIT policies and procedures. For example, a reconciliation of costs incurred compared actual expenditures of UT Southwestern could be performed, prior to submission of the FSR to CPRIT, to identify expenditures that have not been paid.

Management Response: Sponsored Programs Administration (SPA) has recently undertaken a comprehensive reorganization of the department – addressing key people, processes, policies, procedures, training, and compliance functions. This reorganization will strengthen overall controls and increase the level of fiscal compliance and monitoring activities across sponsored programs activities – particularly those activities related to financial status reporting (FSR).

In accordance to CPRIT staff instructions, UT Southwestern staff is aware that incurred, allowable expenses submitted on the FSR should not include accrued costs, included expense not yet paid, which are non-reimbursable expenses on CPRIT awards. While UT Southwester is used to accrual accounting expenses being counted as reimbursable expenses on all other Federal and



ISSUED: AUGUST 31, 2015

Non-Federal research awards, in UT Southwestern's research portfolio, UT Southwestern has agreed with CPRIT staff to perform an additional CPRIT only reconciliation, of costs incurred with actual expenditures, prior to submission of a CPRIT FSR.

We believe this low value/immaterial finding to be an isolated incident. UT Southwester will continue to review transactions at multiple levels during the preparation of the FSR. Additionally, in accordance to CPRIT single audit recommendations of Grant Thornton for FY14, Sponsored Programs Administration has sought clarification on the issue of whether expenses have to be paid prior to a grantee requesting reimbursement (cash only accounting; accruals not allowed). We will continue to seek written clarification form CPRIT and UT System. We will continue to see explicit inclusion of the rule (cash only accounting; accruals not allowed) into the CPRIT Policies/Procedures, CPRIT award notice terms and conditions and CPRIT website.

In parallel, UT Southwestern will continue to define, clarify, document and implement processes and procedures which assure it liquidates obligations, reconciles, and reports sponsored program awards in a timely manner. Further, UT Southwestern will continue to monitor all sponsored award activities to help mitigate risk, increase efficiencies, and encourage fiscal compliance to the maximum extent possible.

Responsible Party: David Ngo, Assistant Vice President, Sponsored Programs Administration **Implementation Date:** October 2015

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University of Texas Health Science Center Houston

Our procedures included interviewing key personnel within the Grants and Sponsored Projects Administration Departments of University of Texas Health Science Center Houston to gain an understanding of the corrective actions taken in order to address the findings identified in their 2014 CPRIT Internal Audit Report, as well as examining existing documentation and performing testing in order to validate those corrective actions. We evaluated the existing policies, procedures, and processes in their current state.

We selected a sample of five active grants over which to perform our procedures: R1215, R1307, R1006, PP120086, and RP140103.

FY 14 Finding 1: Cutoff of Reimbursement Claims – Five expenditures, totaling approximately \$53,000, were incurred within the dates of the FSR period in which they were submitted; however, the payment date was outside of the FSR period.

Procedures Performed: We interviewed the personnel responsible for grant administration and expenditures to gain an understanding of the policies and procedures implemented to ensure proper cutoff of expense reimbursement claims requested in FSRs. We selected a sample of 50 transactions across the five sampled grants for the period of August 2014 through June 2015, and obtained supporting documentation for each expenditure. We verified that the costs requested for reimbursement related to a valid expense, ensured that it was requested in the correct period and ensured that it was paid by the grantee during the period covered by the FSR.

Results: We identified that UTHSC Houston did not take corrective action to remediate the findings identified in the 2014 Internal Audit. Additionally we identified that 36 of the 50 transactions examined were not reported in the correct FSR.

Finding 01 – **HIGH** – No corrective action was taken by UT Health Science Center-Houston in order to remediate the prior year finding. Thirty-six of 50 transactions selected for testing were not paid by UTHSC Houston prior to the period end of the FSR on which they were reported. CPRIT policies and procedures dictate that reimbursement claims should not be made until the period in which the funds are disbursed.

Recommendation: Management should implement policies and procedures in order to ensure grants are administered in accordance with CPRIT policies and procedures and expenditures are included in the appropriate FSR. For example, reconciliation of costs incurred compared actual expenditures of UTHSC Houston could be performed, prior to submission of the FSR to CPRIT, to identify expenditures that have not been paid.

Management Response: UTHealth contends that expenditures are accounted for appropriately under standard accepted accounting practices used for all funding agencies. This practice allows for activities to continue unabated toward successful completion of project objectives and for timely remuneration for services performed.

UTHealth does not seek reimbursement for expenses that have not been disbursed. The Financial Status Reports (FSR) are due 90 days after the end of the reporting period. At the time of FSR submission to CPRIT, all expenses have been disbursed. In addition, CPRIT oftentimes pays six months to a year after the submission of the FSR.

ISSUED: AUGUST 31, 2015

UTHealth objects to this finding as we employ standard accrual accounting for reporting/billing and FSRs to CPRIT occur after the expenditures have been disbursed. Accrual accounting is accepted at the end of the award period by CPRIT, but it is unclear why it is not acceptable for the other billing periods. The requirement to use a "cash methodology" during the FSR reporting period imposes additional administrative and fiscal burden on UTHealth as outlined below. This process will require every expense to be manually reviewed for each billing period prior to FSR submission.

Examples of additional administrative fiscal burden:

- 1. Included in the list of findings are several end of reporting period payroll items. Prudent banking practices dictate payroll be transmitted to the institution's bank three days in advance to ensure availability of funds at the employees' bank on "pay day". The funds have been fully committed to the bank and are applicable payroll costs for the period between the 16th and the final day of each month. These costs are applicable to the reporting period, but this finding infers that we must back out the majority of expenses for the final month of each quarter.
- 2. On July 24, 2015, UTHealth received payments from CPRIT totaling \$407,934.14 for expenses incurred June-August 2014—almost one full year in arrears. An additional \$391,146.16 was also received that day, the majority of which dated back to the period September-November, 2014. Thus, UTHealth has carried a deficit of \$799,980.30 for six months to a year. This amount does not include most billings for the period December-February 2015 (billed in May 2015) which remain unpaid as of today's date.
- CPRIT has continued to enforce new guidelines without modifying its policies/procedures. For example, on July 24, 2015, UTHealth received an email from CPRIT (excerpt below) requiring the following items which have been imposed verbally for a number of months/years.
 - a. UTHealth must submit the Non-Key CPRIT Grant Personnel Update Form each time non-key personnel on a CPRIT funded project changes. This is used to verify personnel information submitted on FSRs.
 - b. Submission of invoices to support all costs reported in Equipment and Contractual line items.
 - c. Submission of invoices to support any expenses with a value of \$750 or more reported in the "Other" and "Supplies" line items.
 - d. Submission of receipts when claiming actual meal costs, not per diem, associated with travel.

Responsible Party: NA Implementation Date: NA

JULY 31, 2015 ISSUED: AUGUST 31, 2015

University of Texas at Austin

Our procedures included interviewing key personnel within the Office of Sponsored Projects of the University of Texas at Austin to gain an understanding of the corrective actions taken in order to address the findings identified in their 2014 CPRIT Internal Audit Report, as well as examining existing documentation and performing testing in order to validate those corrective actions. We evaluated the existing policies, procedures, and processes in their current state.

We selected a sample of four active grants over which to perform our procedures: R1120, R1106, RP110532-P1, and RP120194.

FY 14 Finding 1: Consistency of Expenditure Classification – Inconsistencies in the categorization of the supply of mice and the care of the mice in a central animal resource center – the interdepartmental charges were categorized as both 'other' and 'supplies' in different FSRs.

Procedures Performed: We interviewed the personnel responsible for grant administration and expenditures to gain an understanding of the policies and procedures implemented to ensure the consistent classification of expenditures. We obtained a memorandum prepared by UT Austin that details the proper allocation of costs for grant expenditures. We selected a sample of 50 transactions across the four sampled grants for the period of August 2014 through June 2015, and obtained supporting documentation for each expenditure. We verified that the costs requested for reimbursement were accurately and consistently classified according to the memorandum and budget submitted to CPRIT.

Results: Finding remediated.

FY 14 Finding 2: Improper Tracking of Inventory and Equipment – For one inventory item sampled, the serial number from CPRIT's annual inventory report differed from the serial number observed on the piece of inventory.

Procedures Performed: We interviewed the personnel responsible for grant administration and expenditures to gain an understanding of the policies and procedures implemented to ensure that inventory and equipment location is appropriately recorded and tracked. We also obtained the listing of inventory and equipment purchased with CPRIT grant funds. We verified the equipment location and tag number were accurate and consistent with the location and tag number recorded in the listing.

Results: Finding remediated.

ISSUED: AUGUST 31, 2015

Texas Nurses Foundation

Our procedures included interviewing key personnel within the Finance Department of Texas Nurses Foundation to gain an understanding of the corrective actions taken in order to address the findings identified in their 2014 Internal Audit Report, as well as examining existing documentation and performing testing in order to validate those corrective actions. We evaluated the existing policies, procedures, and processes in their current state.

We performed our procedures over the two active grants for Texas Nurses Foundation, PP110102 and PP120177.

FY 14 Finding 1: Subjective Allocation of Employee Time - Allocation of Nurse Oncology Education Program (NOEP) employee time spent on the CPRIT grant was subjective. An estimated percentage of time spent on each grant area was determined by the program staff and not tracked on timesheets. Compensation, taxes, and benefits were expensed to CPRIT based on this allocation. The total amount claimed over the period of the grant for these categories of expenses was \$106,588; therefore an inaccurate allocation of time could be material to the grant as a whole.

Procedures Performed: We interviewed the Finance Director of Texas Nurses Foundation to gain an understanding of the policies and procedures implemented to allocate the compensation, taxes and benefits of their NOEP employees to CPRIT grants. We obtained and examined updated policies of Texas Nurses Foundation and verified that they adequately address the tracking and allocation of payroll and benefit costs to be allocated to CPRIT grants. We also selected a sample of 25 payroll and benefits expenditures for the period of July 2014 through June 2015 to ensure that they were correctly calculated, appropriately allocated, according to the updated policies, and that the costs were directly related to work on CPRIT grants.

Results: Finding remediated.

FY 14 Finding 2: Reimbursement Claims for Payroll and Benefits Maintained Separately – NOEP's reimbursement claims for payroll and benefit amounts were maintained separately from the other CPRIT expenses making it difficult to substantiate the figures allocated.

Procedures Performed: We interviewed the Finance Director of Texas Nurses Foundation to gain an understanding of the policies and procedures implemented to allocate the compensation, taxes and benefits of their NOEP employees to CPRIT grants. We obtained and examined updated policies of Texas Nurses Foundation and verified that they adequately address the tracking and allocation of payroll and benefit costs to be allocated to CPRIT grants. Through our testing of payroll and benefits transactions in Finding 1, we verified that documentation to support the compensation, tax and benefit costs allocated to CPRIT grants was appropriately maintained with reimbursement claims.

Results: Finding remediated.

FY 14 Finding 3: Lack of Documentation to Substantiate Allocation of Expenditures – The allocation of certain expenses across various grants was unsubstantiated. Internal Audit noted that in one instance, a receipt of \$297.47 for office supplies was split between two grants, one from CPRIT and one from another organization; however, there was no clear documentation behind the allocation of funds between the two grants.

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Procedures Performed: We interviewed the Finance Director of Texas Nurses Foundation to gain an understanding of the policies and procedures implemented to document the allocation of expenditures to more than one grant. We obtained and examined the updated policies of Texas Nurses foundation and verified that they adequately address the allocation of grant expenditures to multiple grants. We also selected 25 transactions across the two grants for the period of July 2014 through June 2015, and verified that the costs were allowable and had adequate documentation to support their allocation to their respective grant.

Results: Finding remediated.

FY 14 Finding 4: Unallowable Marketing Expenditures – A combined unallowable expense of \$1,729.35 was claimed for the purchase of lip balms used for promotional purposes. Promotional expenditure is specifically unallowable per CPRIT's policies and procedures.

Procedures Performed: We interviewed the Finance Director of Texas Nurses Foundation to gain an understanding of the policies and procedures implemented to approve expenditures requested for reimbursement in Financial Status Reports (FSRs). We obtained and examined the updated policies of Texas Nurses Foundation and verified that they address the review and approval of expenditures requested for reimbursement. We also selected 25 transactions across the two grants for the period of July 2014 through June 2015, and verified that the costs, including marketing expenditures, were allowable according to the grant terms and detailed grant budget approved by CPRIT.

Results: Finding remediated.

FY 14 Finding 5: Unallowable IT Expenditures – An unallowable expense of \$315 was claimed for the lease of IT equipment as part of the Financial Status Report. This type of expenses was not included as part of the detailed budget agreed upon by CPRIT.

Procedures Performed: We interviewed the Finance Director of Texas Nurses Foundation to gain an understanding of the policies and procedures implemented to approve expenditures requested for reimbursement in Financial Status Reports (FSRs). We obtained and examined the updated policies of Texas Nurses Foundation and verified that they address the review and approval of expenditures requested for reimbursement. We also selected 25 transactions across the two grants for the period of July 2014 through June 2015, and verified that the costs, including IT expenditures, were allowable according to the grant terms and detailed grant budget approved by CPRIT.

Results: Finding remediated.

FY 14 Finding 6: Incorrect Classification of Expenditures – Travel expenses of \$322.72 were incorrectly allocated to the 'supplies' category and another \$194.58 incorrectly allocated to the 'other' category.

ISSUED: AUGUST 31, 2015

Procedures Performed: We interviewed the Finance Director of Texas Nurses Foundation to gain an understanding of the policies and procedures implemented to approve the classification of expenditures requested for reimbursement in Financial Status Reports (FSRs). We obtained and examined the updated policies of Texas Nurses Foundation and verified that they address the review and classification of expenditures requested for reimbursement. We also selected 25 transactions across the two grants for the period of July 2014 through June 2015, obtained supporting documentation for the expenditure, and verified that the costs were appropriately classified according to the nature of the costs and the detailed budget approved by CPRIT.

Results: Finding remediated.

APPENDIX

JULY 31, 2015 ISSUED: AUGUST 31, 2015

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

REPORT RATINGS

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- · Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
 - o Reliability and integrity of financial and operational information
 - Effectiveness and efficiency of operations and programs
 - o Safeguarding of assets
 - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.

The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.

The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.



ISSUED: AUGUST 31, 2015

RISK RATINGS

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the Institute or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the organization
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

IA # 04-15 - INTERNAL AUDIT REPORT OVER EXPENDITURES

REPORT DATE: AUGUST 24, 2015

ISSUED: OCTOBER 7, 2015

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The Oversight Committee
Cancer Prevention and Research Institute of Texas
1701 North Congress Avenue, Suite 6-127
Austin, Texas 78701

This report presents the results of the internal audit procedures performed for the Cancer Prevention and Research Institute of Texas (the Institute) during the period August 3, 2015 through August 24, 2015 related to the Institute's expenditures process.

The objectives of this internal audit were to evaluate the design and effectiveness of the Institute's expenditures process. The objectives were organized as follows:

- A. Verify that internal controls over payable expenditures are designed to ensure the effective management of the process and that the relevant risks have corresponding key controls to ensure that payments are only approved, initiated, processed and disbursed for valid expenditures and vendors.
- B. Ensure that the controls in place over high-risk processes are operating effectively to ensure the accuracy of the receipt, review, approval, recording, classification, period and payment of payable expenditures is complete and accurate.

To accomplish these objectives, we conducted interviews with key personnel responsible for expenditures. We also reviewed documentation and performed specific testing procedures to assess controls. Procedures were performed at the Cancer Prevention and Research Institute of Texas office and were completed on August 24, 2015.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

WEAVER AND TIDWELL, L.L.P.

Weaver and Siduell, L.S.P.

Austin, Texas October 7, 2015

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 04-15 INTERNAL AUDIT REPORT OVER EXPENDITURES AUGUST 24, 2015

ISSUED: OCTOBER 7, 2015

BACKGROUND

The Cancer Prevention and Research Institute of Texas (CPRIT or the agency) expends funds for both the operations of the agency and to reimburse the expenditures of other organizations as part of a grant reimbursement. Expenditures related to the reimbursement of grant funds originate through the grants management process and were included with the Grants Management Internal Audit. Expenditures related to the operations of the agency for expenses such as travel, legal, consulting, auditing, IT expenses, construction/remodeling costs, and other recurring operating expenditures such as utilities and rents. Invoices for expenditures are received by CPRIT's Accountant, matched to Purchase Orders, routed for review and approval, and then entered into the Uniform Statewide Accounting System (USAS) for payment.

AUDIT OBJECTIVE AND SCOPE

The audit focused on the Payable Expenditures process in place at CPRIT. We reviewed the procedures for appropriate risk and regulatory coverage and compliance with CPRIT and State requirements. We evaluated the design and effectiveness of the process to ensure that payments are only approved, initiated, processed and disbursed for valid expenditures and vendors. Key function and sub-processes within the Payable Expenditure process that were reviewed include:

- Receipt, validation and approval of payable invoices
- Recording and classification of payable invoices
- Payment date identification, entry and validation
- Authorization of payments
- Disbursement of funds

The audit did not include the purchasing, payroll or grant administration processes except as they pertain to the release of funds.

Our procedures were designed to ensure relevant risks are covered and verified the following:

Receipt, Validation and Approval of Payable Invoices

- Invoices for goods and services are received in a timely manner
- Invoices and vouchers are properly reviewed
- Invoices and vouchers match purchase orders or requisitions
- Invoices and vouchers are approved by appropriate personnel
- Expenses are valid
- Duties to review and approve invoices are appropriately segregated

Recording and Classification of Payable Invoices

- Vouchers for approved invoices are created and recorded in USAS in a timely manner
- Vouchers are recorded in the proper period
- Vouchers are coded to the correct account
- All invoices and vouchers are recorded

Payment Date Identification, Entry, and Validation

- Valid payment dates are identified for invoice payment
- Payment dates are in compliance with policies and procedures
- Vouchers are paid within required terms
- Vouchers are monitored to ensure disbursements are in compliance with State requirements



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 04-15 INTERNAL AUDIT REPORT OVER EXPENDITURES AUGUST 24, 2015

ISSUED: OCTOBER 7, 2015

Authorization of Payments

- Distribution of funds are authorized by proper personnel
- · Authorization to release payment is appropriately segregated
- Payments for all approved vouchers are made in a timely manner
- Payments are reconciled back to invoices and vouchers
- Payments are made for the correct amount

Disbursement of Funds

- Disbursements are not for fictitious and duplicate transactions
- Segregation of duties are appropriate
- Funds are disbursed only after proper authorization
- Disbursed amounts agree with the amount paid
- Disbursements are recorded when paid
- Encumbrances are completely and accurately relieved

The objectives of this internal audit were as follows:

- A. Verify that internal controls over payable expenditures are designed to ensure the effective management of the process and that the relevant risks have corresponding key controls to ensure that payments are only approved, initiated, processed and disbursed for valid expenditures and vendors.
- B. Ensure that the controls in place over high-risk processes are operating effectively to ensure the accuracy of the receipt, review, approval, recording, classification, period, and payment of payable expenditures is complete and accurate.

Our procedures included interviewing key personnel within the Accounting and Operations groups to gain an understanding of the current processes in place, examining existing documentation, evaluating the internal controls over the process, and testing the effectiveness of the controls in place. We evaluated the existing policies, procedures and processes in their current state. Our coverage period was from July 1, 2014 through June 30, 2015.

EXECUTIVE SUMMARY

Through our interviews, evaluation of internal control design and testing of transactions we identified two findings. The listing of findings include those items that have been identified and are considered to be non-compliance issues with documented CPRIT policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover significant risks to CPRIT. These issues could have significant financial or operational implications.

A summary of our results, by audit objective, is provided in the table below. See the Appendix for an overview of the Assessment and Risk Ratings.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 04-15 INTERNAL AUDIT REPORT OVER EXPENDITURES AUGUST 24, 2015

ISSUED: OCTOBER 7, 2015

OVERALL ASSESSMENT

SCOPE AREA	RESULT	RATING
Objective A: Verify that internal controls over payable expenditures are designed to ensure the effective management of the process and that the relevant risks have corresponding key controls to ensure that payments are only approved, initiated, processed and disbursed for valid expenditures and vendors.	Tracking invoices received, but not recorded in USAS Invoice validation and payment authorization segregation of duties	STRONG
Objective B: Ensure that the controls in place over high-risk processes are operating effectively to ensure the accuracy of the receipt, review, approval, recording, classification, period, and payment of payable expenditures is complete and accurate.	our testing.	STRONG

Other opportunities for improvement were identified through our interviews, evaluation of internal control design and transactional testing. These observations include those items that are not considered to be non-compliance issues with documented agency policies and procedures. These are considered process improvement observations and the intent for the recommendations are to strengthen current agency processes and controls. These observations were provided to management separately

CONCLUSION

Based on our evaluation, the expenditures function has procedures and controls in place to conduct effective management of the significant processes within CPRIT. However, we identified opportunities to improve the processes within the Payable Expenditures process.

CPRIT should implement an invoice tracking system in order to ensure that all invoices received are routed for the proper approvals and entered into USAS to be paid. Additionally, CPRIT should ensure that all invoices are reviewed for validity and authorized for payment by separate individuals who have the proper authority and knowledge of the services or goods provided.

STRONG

DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 04-15 INTERNAL AUDIT REPORT OVER EXPENDITURES AUGUST 17, 2015

ISSUED: OCTOBER 16, 2015

DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

Our procedures included interviewing key personnel within the Accounting and Operations groups to gain an understanding of the current processes in place, examining existing documentation, evaluating the internal controls over the process, and testing the effectiveness of the controls in place. We evaluated the existing policies, procedures and processes in their current state.

Objective A: Design of Internal Controls

Verify that internal controls over payable expenditures are designed to ensure the effective management of the process and that the relevant risks have corresponding key controls to ensure that payments are only approved, initiated, processed and disbursed for valid expenditures and vendors.

- Procedures Performed: We gained an understanding of the current expenditures process by conducting interviews with key personnel; reviewing existing procedures, standardized forms and documents used by CPRIT's personnel; and assessing the CPRIT's administrative rules to identify key controls. We examined the following sub-processes:
 - Receipt, validation and approval of payable invoices
 - · Recording and classification of payable invoices
 - · Payment data identification, entry and validation
 - Authorization of payments
 - Disbursement of funds

We evaluated the controls identified against expected controls to determine whether the identified reoccurring expenditures procedures and internal controls are sufficiently designed to mitigate all critical risks associated with the process. We also identified unacceptable risk exposures due to control design inadequacy and opportunities to strengthen the effectiveness and efficiency of the existing control design.

Results: We identified 11 controls in place over the significant activities within the expenditures function. We identified two findings where improvements in the processes, polices, and procedures can be made.

Finding 1 – LOW – Invoice Tracking: The current CPRIT invoice processing procedures do not have controls in place to ensure that all invoices received and routed for approval are returned to the Accountant and entered into USAS to be processed for payment. Invoices are stamped with their received date, but there is no formalized method to track invoices through the process of routing for approval and entry into USAS.

Recommendation: CPRIT should maintain a log of all received invoices in order to have a record of all invoices that have been submitted to the agency. Invoices should be recorded in the log upon their receipt and prior to being routed for approval. The log should include the date received, invoice number, vendor, the employee to whom the invoice was routed for approval, and the status of the invoice in the approval and payment process. The log should be reviewed on a monthly basis to ensure that all invoices received by CPRIT have been posted to USAS for payment.

CPRIT Management Response: CPRIT management agrees that a log of invoices received by the agency should be developed to track invoices through the payment process. CPRIT will establish a process to review the log on a monthly basis, comparing the logged invoices to payments posted in the document register.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 04-15 INTERNAL AUDIT REPORT OVER EXPENDITURES AUGUST 17, 2015

ISSUED: OCTOBER 16, 2015

Responsible Party: Chief Operating Officer, Accountant

Date: November 1, 2015

Finding 02 – LOW – Segregation of Duties: The COO reviews and approves audit service invoices for validity of the expense and payment as well as authorizes the release of funds for the same invoices. There is not an initial reviewer to segregate the validation of the invoice, allowing an independent individual to provide oversight and approval over the payment of those invoices.

Recommendation: CPRIT should segregate the duty to review invoices for validity and to authorize their payment. Service invoices could be reviewed by the Operations Manager and payment could be authorized by the COO. Alternatively the COO could review the invoices for validity and another officer of the agency could authorize the invoice for payment.

CPRIT Management Response: CPRIT management agrees that the review of the validity of invoices and the authorization of the payment of invoices should be segregated. When the Chief Operating Officer serves as the contract administrator for a service contract and reviews invoices related to that contract for validity, the Chief Executive Officer must sign the purchase voucher to authorize payment.

Responsible Party: Chief Operating Officer, Accountant

Date: November 1, 2015

Objective B: Effectiveness of Controls

Ensure that the controls in place over high-risk processes are operating effectively to ensure the accuracy of the receipt, review, approval, recording, classification, period, and payment of payable expenditures is complete and accurate

- 1. Procedures Performed: We selected a sample of 50 payables expenditures during the scope period of June 1, 2014 through July 31, 2015. For each expenditure, we obtained supporting evidence and verified the following:
 - Expenditure amounts agreed to the invoice and corresponding purchase order
 - Invoices were appropriately reviewed, approved, and authorized for payment
 - Vouchers for payment were entered and released in USAS by separate personnel
 - Coding of the expense is accurate and appropriate
 - Disbursements were made on a timely basis and in accordance with the Prompt Payment Act
 - If applicable, interest was appropriately calculated, applied to the payment, and disbursed to the vendor
 - Amounts disbursed were appropriately reviewed and approved

Results: No findings identified.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 04-15 INTERNAL AUDIT REPORT OVER EXPENDITURES AUGUST 17, 2015 ISSUED: OCTOBER 16, 2015

2. Procedures Performed: We selected a sample of two months during the scope period of June 1, 2014 through July 31, 2015. For each month, we obtained supporting documentation and verified the

following:

The monthly reconciliation between USAS and the manual Document Register was prepared by the Accountant and reviewed by the COO. This reconciliation focuses on differences related to coding, dates and amounts between USAS and the manual Document Register.

Results: No findings identified.

3. Procedures Performed: We selected a sample of two months during the scope period of June 1, 2014 through July 31, 2015. For each month, we obtained supporting documentation and verified the following:

• The budget report to track expenditures and open purchase orders against the budget was appropriately prepared, reviewed, and approved.

Results: No findings identified.

4. Procedures Performed: We obtained the access settings to the secured drives that contain the Document Register that is used to maintain a listing of all agency expenditures and verified that the access to modify the Document Register is appropriately restricted.

Results: No findings identified.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 04-15 INTERNAL AUDIT REPORT OVER EXPENDITURES AUGUST 17, 2015

ISSUED: OCTOBER 16, 2015

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

REPORT RATINGS

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
 - o Reliability and integrity of financial and operational information
 - o Effectiveness and efficiency of operations and programs
 - Safeguarding of assets
 - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong

The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.

Satisfactory

The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.

Unsatisfactory

The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 04-15 INTERNAL AUDIT REPORT OVER EXPENDITURES AUGUST 17, 2015

ISSUED: OCTOBER 16, 2015

RISK RATINGS

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or group
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior Institute management

Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the agency or across more than one function of the Institute
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the organization
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS INTERNAL AUDIT RISK ASSESSMENT REPORT AUGUST 31, 2015

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Oversight Committee Cancer Prevention and Research Institute of Texas 1701 North Congress Avenue, Suite 6-127 Austin. Texas 78701

We have completed our internal audit risk assessment, which included establishing a risk-based, prioritized internal audit universe for the Cancer Prevention and Research Institute of Texas (CPRIT or the agency). Enclosed you will find the following documentation which depicts the results of the assessment:

- Risk Rated Significant Activity Summary
- Risk Assessment Risk Map
- Internal Audit History Over Significant Activities
- Proposed 3-Year Internal Audit Plan

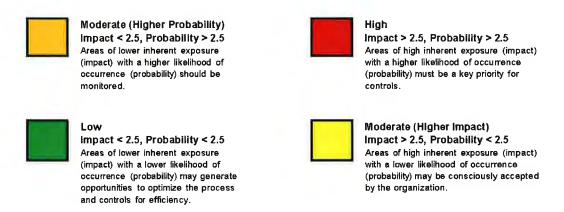
Our risk assessment was performed on August 28, 2015, in accordance with the applicable Standards for the Professional Practice of Internal Auditing as prescribed by the Institute of Internal Auditors. The risk assessment process and the resulting risk-ranked internal audit universe were completed based on the existing business conditions present at the time of the assessment. The audit universe and risk rankings should be periodically updated to appropriately reflect the changing risk profile of the agency as organizational changes occur.

A risk assessment is performed to measure the influence of various risk categories as they affect the significant functions of CPRIT. The risk categories and their definitions are provided in the Appendix. They include financial and fraud; operation, complexity and human capital; information technology; regulatory, compliance, and public policy; and reputational. The risk rated audit universe for the agency was designed by weighting risk factors in each area and establishing an overall risk-rank for each process. The risks were assessed for each process on the basis of the inherent risk related to each process. Inherent risk is the risk related to a process in its uncontrolled state, without consideration of any control activities the agency may have implemented to address those risks. The tables on the attached pages represent the risk-rated internal audit universe. Each significant activity has been plotted onto the risk map to visually illustrate the overall balance of the universe.

Risk represents the degree of likelihood and the duration of time that an unfavorable event will significantly impact a functional area's ability to meet the agency's objectives as well as the speed at which that impact would occur.

- Probability The likelihood that the risk category intentionally or unintentionally influences the significant financial and operational activities of the organization.
- Impact The magnitude of the influence that a risk category bears over the significant financial and operational activities of the organization, including consideration of persistence and velocity.
 - Velocity The speed at which the impact affects the organization after the occurrence of an influential event.
 - Persistence The duration of time which influential events naturally occur within a risk category.

Risk maps have been prepared for the internal audit universe. The risk maps were designed to be a visual representation of the risk profile of the agency. The risk maps plot each audit area based on its probability of error, fraud or misstatement, and the area's impact on the agency resulting from potential error, fraud or misstatement. Areas plotted in the red region should be considered for evaluation in the upcoming year, while areas in the yellow and green regions can be evaluated in future periods. The risk maps are split into four quadrants that assist in prioritizing response efforts to ensure higher risk areas are evaluated first. The four quadrants are described below:



We have provided an Internal Audit History which documents the audits conducted for the past three years over significant processes. We have considered the prior internal audits conducted within the past three years as well as changes being implemented within the CPRIT compliance function.

In consultation with CPRIT's management, we have prepared a recommended three-year Internal Audit Plan for the agency. The audit plan takes into consideration the results of the risk assessment, historical internal audit activities, and additional input from CPRIT management. The Internal Audit Plan includes a schedule of auditing at least three high or moderate risk processes per year. The proposed Three-Year Internal Audit Plan is included in the Appendix for your review and approval.

The agency should develop and implement internal audit steps and fraud prevention action plans to obtain reasonable reassurance that control activities are in place to adequately address the risks identified for all significant process areas as part of the risk assessment.

If you have any questions or concerns please contact me directly. We have enjoyed working with you throughout this process.

Sincerely,

Alyssa G. Martin

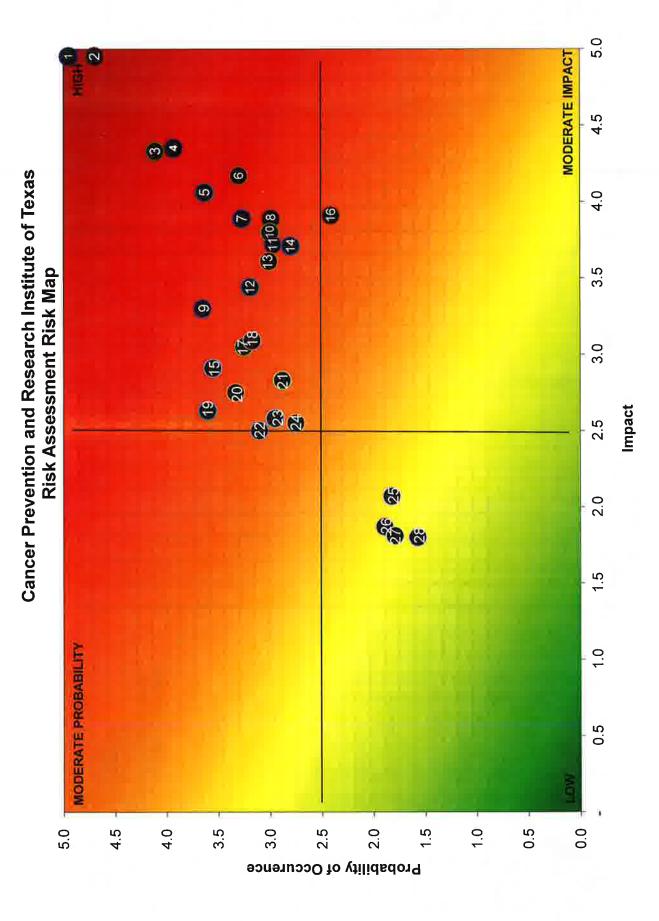
Partner, Risk Advisory Services

October 16, 2015

Cancer Prevention and Research Institute of Texas Risk Rated Significant Activity Summary August 2015

							2015	2015 Risk Assessment	essment					
		Financial and Fraud	ial and ud	Operational, Complexity and Human Capital	tional, kity and Capital	Information Technology	ation	Regulatory, Compliance and Public Policy	tory, ce and	Reputation	ation		Composite	
		22%	%	20%	%	15%	%	23%		20%	%	100%	100%	Total
Ranking	SIGNIFICANT ACTIVITIES	Ь	1	Ь	0	4	-	۵		۵	-	Ь		
1	Pre-Award Grant Management	5	5	5	2	2	2	2	2	2	5	5.00	5.00	5.00
2	Post-Award Grant Monitoring	5	5	5	2	3	5	5	5	5	2	4.70	5.00	4.86
3	Information Security	2	3	5	5	5	5	4	4	5	5	4.11	4.33	4.22
4	Commodity and Service Contracts	4	5	3	4	2	2	5	5	5	5	3.93	4.35	4.14
2	Governance	3	3	4	4	3	3	4	5	4	5	3.63	4.06	3.85
9	Procurement	3	5	4	2	-	1	3	4	2	5	3.30	4.17	3,74
7	Information Technology Services	3	4	4	5	2	5	2	2	3	4	3.27	3.89	3.58
8	Grant Contracting	4	4	3	3	2	3	4	4	3	4	3.30	3.65	3.48
6	Non-Grant Expenditures	4	5	2	3	3	3	2	3	4	5	2.99	3.84	3.42
10	Training	3	4	3	3	3	4	3	4	3	4	3.00	3.80	3.40
11	Cash Management	3	4	4	3	3	4	2	3	3	5	2.97	3.77	3.37
12	Budget and Planning	4	2	4	3	3	3	2	3	3	3	3.19	3.44	3.32
13	External Affairs	1	2	4	4	2	3	3	4	5	5	3.01	3.61	3.31
14	Revenue	2	3	3	3	2	2	2	5	5	5	2.80	3.71	3.26
15	State Reporting Requirements	1	3	4	4	4	4	3	3	3	4	2.91	3.55	3.23
16	Oversight Committee Reporting	1	3	3	4	2	2	3	5	3	2	2.41	3.91	3.16
17	Application Development	2	2	4	4	5	5	2	2	3	4	3.05	3.25	3.15
18	Event Management	3	3	4	3	4	3	1	2	4	5	3.09	3.17	3.13
19	Human Resource Administration	2	3	4	5	2	3	3	3	2	4	2.63	3.60	3.12
20	Financial Close and Reporting	2	2	4	4	3	4	2	3	3	4	2.75	3.33	3.04
21	Communications	1	1	3	3	2	4	2	2	4	5	2.83	2.88	2.86
22	Purchasing Cards	3	3	2	3	1	1	3	3	3	5	2.50	3.10	2.80
23	Payroll (DHHS Inter-Agency Contract)	2	3	3	3	3	4	3	3	2	2	2.58	2.95	2.77
24	External Communications/Advocacy	2	2	2	2	3	3	2	2	4	5	2.55	2.75	2.65
25	Travel (In and Out of State)	3	2	2	2	1	1	2	1	2	3	2.07	1.82	1.95
26	Facilities and Maintenance	3	3	2	2	1	1	2	1	1	2	1.87	1.84	1.86
27	Benefits Administration	-	1	2	2	2	2	3	3	,	1	1.81	1.81	1.81
28	Capital Assets	2	2	2	2	2	2	2	-	-	-	1.80	1.57	1.69





Cancer Prevention and Research Institute of Texas Risk Legend

Process Area	State Reporting Requirements	Oversight Committee Reporting	Application Development	Event Management	Human Resources Adminstration	Financial Close and Reporting	Communications	Purchasing Cards	Payroll (DHHS Inter-Agency Contract)	External Communications/Advocacy	Travel (In and Out of State)	Facilities and Maintenance	Benefits Administration	Capital Assets
Matrix Position	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Low	Low	Low	Low
Plot	15	16	17	18	19	20	21	22	23	24	25	26	27	28
Process Area	Pre-Award Grant Management	Post-Award Grant Monitoring	Information Security	ity and Service Contracts	ıce	Procurement	n Technology Services	itracting	t Expenditures		nagement	nd Planning	Affairs	
	Pre-Aw	Post-Aw	Informati	Commod	Governar	Procurem	Informatio	Grant Cor	Non-Gran	Training	Cash Mar	Budget a	External	Revenue
Matrix Position	_	_						Moderate Grant Cor				Moderate Budget a		Moderate Revenue



Cancer Prevention and Research Institute of Texas Internal Audit History Over Significant Activities August 2015

This schedule identifies the historical internal audits performed within the past 3 years over significant activities.

Ranking	dule identifies the historical internal audits parti	Overall Average	2013 Audits	2014 Audits	2015 Audits	Consider for Internal Audit (2016-2018)	Recommendation
1	Pre-Award Grant Management	6,00	Grants Management	Grants Management	Grants Management	х	Follow-up in 2016 Internal Audit Plan 2018 Internal Audit Plan
2	Post-Award Grant Monitoring	4.00	Grants Management	Grants Management	Grants Management	х	Follow-up in 2016 Internal Audit Plan 2018 Internal Audit Plan
3	Information Security	8.22				х	2016 Internal Audit Plan
4	Commodity and Service Contracts	4.11	Expenditures	Expenditures		х	2016 Internal Audit Plan
5	Governance	3.88		Governance	Governance and IT Follow-Up		
6	Procurement	3,74	Expenditures	Expenditures		х	2017 Internal Audit Plan
7	Information Technology Services	3.58	Information Technology	Information Technology	Governance and IT Follow-Up	х	Follow-up in 2016 Internal Audit Plan 2018 Internal Audit Plan
8	Grant Contracting	3.48	Grants Management	Grants Management	Grants Management	х	Follow-up in 2016 Internal Audit Plan
9	Non-Grant Expenditures	3.42	Expenditures	Expenditures	Expenditures	х	2017 Internal Audit Plan
10	Training	3.40				х	2017 Internal Audit Plan
11	Cash Management	3.37				х	2016 Internal Audit Plan
12	Budget and Planning	3.32				х	2018 Internal Audit Plan
13	External Affairs	3.31				х	2017 Internal Audit Plan
14	Revenue	3.26				x	2016 Internal Audit Plan
15	State Reporting Requirements	3.23					=======================================
16	Oversight Committee Reporting	3.16					
17	Application Development	3.15					
18	Event Management	3.13					
19	Human Resource Administration	3.12					
20	Financial Close and Reporting	3.04					
21	Communications	2.86					
22	Purchasing Cards	2.80					
23	Payroll (DHHS Inter-Agency Contract)	2.77					
24	External Communications/Advocacy	2.65					
25	Travel (In and Out of State)	1.95					
26	Facilities and Maintenance	1,86					
27	Benefits Administration	1:81					
28	Capital Assets	1.69					

Cancer Prevention and Research Institure of Texas Three-Year Internal Audit Plan August 2015

Audit Area	Risk Rating	Summary Procedures	Project Type
		2016 Planned New Internal Audits	
Information Security	High	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Information Security practices. Activities to be evaluated will include Internal and External Security, Logical Access, Physical Access, Risk Assessment, and Compliance with security and privacy requirements.	Internal Audit
Commodity and Service Contracts	High,	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Commodity and Service Contracts practices. Activities to be evaluated will include Contract Compliance, Contract Management and Professional Services.	Internal Audit
Revenue	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Revenue practices. Activities to be evaluated will include General Obligation Bonds, License Plate Fees, Application Fees, Revenue Sharing and Other Revenue Sources.	Internal Audit
Cash Management	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Cash Management practices. Activities to be evaluated will include Electronic Funds Transfer Processing, State Treasury Reconciliations and Cash Forecasting.	Internal Audit
		2016 Planned Internal Audit Follow-up	
Pre-Award Grant Management Post-Award Grant Management Grant Contracting	нан	Internal Audit will perform follow-up procedures on 2015 Internal Audit findings to ensure corrective action has been taken.	Follow-up
Information Technology Services	Moderate	Internal Audit will perform follow-up procedures on 2015 Internal Audit findings to ensure corrective action has been taken.	Follow-up
		2016 Planned Annual Requirements	
Project Management	NA	Track overall internal audit procedures, coordinate audit activities, and reporting to management.	Project Management
Update Risk Assessment	NA	Perform required annual update of risk assessment.	Policy Compliance
Annual and Quarterly Board Reports	AN	Prepare and submit required Annual Internal Audit Report and quarterly reports to the Audit Subcommittee and Oversight Committee of internal audit activities.	Policy Compliance

Cancer Prevention and Research Institure of Texas Three-Year Internal Audit Plan August 2015

Audit Area	Risk Rating	Summary Procedures	Project Type
		2017 Planned New Internal Audits	
Procurement	High	Internal Audit will include an evaluation of risks and internal controls in place related to the CPRIT's Procurement practices. Activities to be evaluated will include Purchase Orders, Bidding and Awards, Contract Negotiation and Approval, Vendor Management and Selection, Vendor Acceptance, and Vendor Set-up.	Internal Audit
Non-Grant Expenditures	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Non-Grant Expenditures process. Activities to be evaluated will include Vendor Invoice Review, Approval and Recording, Vendor Payments, Vendor Monitoring, Travel and Expense Reimbursement, and Independent Contractors.	Internal Audit
Training	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Training practices. Employee Technical Training, Oversight Committee Training, Employee Compliance and Ethics Training, and Grantee Training and Onboarding.	Internal Audit
External Affairs	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's External Affairs practices. Activities to be evaluated will include Governmental Affairs and Public Information processing.	Internal Audit
		2017 Planned Internal Audit Follow-up	
Information Security	High	Internal Audit will perform follow-up procedures on 2016 Internal Audit findings to ensure corrective action has been taken.	Follow-up
Commodity and Service Contracts	High	Internal Audit will perform follow-up procedures on 2016 Internal Audit findings to ensure corrective action has been taken.	Follow-up
Revenue	Moderate	Internal Audit will perform follow-up procedures on 2016 Internal Audit findings to ensure corrective action has been taken.	Follow-up
Cash Management	Moderate	Internal Audit will perform follow-up procedures on 2016 Internal Audit findings to ensure corrective action has been taken.	Follow-up
		2017 Planned Annual Requirements	
Project Management	NA W	Track overall internal audit procedures, coordinate audit activities, and reporting to management.	Project Management
Update Risk Assessment	ΝΑ	Perform required annual update of risk assessment.	Policy Compliance
Annual and Quarterly Board Reports	NA	Prepare and submit required Annual Internal Audit Report and quarterly reports to the Audit Subcommittee and Oversight Committee of internal audit activities.	Policy Compliance

Cancer Prevention and Research Institure of Texas Three-Year Internal Audit Plan August 2015

Audit Area	Risk Rating	Summary Procedures	Project Type
		2018 Planned New Internal Audits	
Pre Award Grant Management	High	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Grants	
Post Award Grant Monitoring	High	Management, Monitoring and Contracting practices. Activities to be evaluated will include RFA Review Process, Conflicts of Interest, Peer Review, Grant Application Approval, Contract Terms, Fund Availability, Certifications, Grant Contract Execution, Grantee Monitoring, Sub-Contractor Monitoring, Grantee Reporting and Scientific	Internal Audit
Grant Contracting	Moderate	Review.	
Information Technology Services	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Information Technology practices. Activities to be evaluated will include Network Operations, Help Desk, Change Management, Website Maintenance, Intranet Content Management, Third-Party Services, Disaster Recovery and Business Continuity Planning.	Internal Audit
Budget and Planning	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Budgeting and Planning practices. Activities to be evaluated will include Budgeting, Forecasting and Planning, Agency Strategic Plan, Budget Review and Amendment, Capital Expenditures, and Budget Monitoring.	Internal Audit
		2018 Planned Internal Audit Follow-up	
Procurement	High	Internal Audit will perform follow-up procedures on 2017 Internal Audit findings to ensure corrective action has been taken,	Follow-up
Non-Grant Expenditures	Moderate	Internal Audit will perform follow-up procedures on 2017 Internal Audit findings to ensure corrective action has been taken.	Follow-up
Training	Moderate	Internal Audit will perform follow-up procedures on 2017 Internal Audit findings to ensure corrective action has been taken.	Follow-up
External Affairs	Moderate	Internal Audit will perform follow-up procedures on 2017 Internal Audit findings to ensure corrective action has been taken.	Follow-up
		2018 Planned Annual Requirements	
Project Management	AN	Track overall internal audit procedures, coordinate audit activities, and reporting to management.	Project Management
Update Risk Assessment	ĄN	Perform required annual update of risk assessment.	Policy Compliance
Annual and Quarterly Board Reports	ΑN	Prepare and submit required Annual Internal Audit Report and quarterly reports to the Audit Subcommittee and Oversight Committee of internal audit activities.	Policy Compliance

APPENDIX

Cancer Prevention and Research Institute of Texas Risk Assessment Definitions

The risk categories presented below are defined specifically for CPRIT based on the results of research of the agency's operations, discussions with management, and based on review and consideration of the Risk Assessment performed in 2013. The risk categories were developed to incorporate the entity level risks identified in the 2013 Risk Assessment and include reference to identified risk events. The risks categories should be considered as they affect the operations, functions, and activities executed by CPRIT and CPRIT personnel as well as external functions and operations that are executed on behalf of CPRIT by third parties as those operations and functions integrate and are part of CPRIT operations.

These risk categories and definitions will also be used for the process level risk assessment in which unique activities across CPRIT will be evaluated to determine the inherent probabili and impact of each of the risks below on CPRIT activities.

Risk ratings should be completed without considering controls in place to millgate risk; therefore, focus on the natural or inherent risk for the activity

Inherent Risk

Natural state of risk in an uncontrolled activity.

The risk assessment is designed to evaluate the probability and impact of inherent risk in the identified activities, this requires each individual to put aside the existing controls so that a true evaluation of the inherent risk within each activity may be assessed.

-	RI	isk Definitions	
Risk Category	Risk Definition	CPRIT Risk Events and Considerations	
	The risk that CPRIT will fail to accurately forecast program target	Inability to develop timely and reasonable budgets and adequately record transactions	
	numbers, record and report financial transactions and adequately manage the disbursements of grant funds. Also includes the risk	Unmanaged changes in costs	
Financial and	manage the disbursements of grant funds. Also includes the risk of the of the occurrence of illegal acts characterized by deceit, concealment or violation of trust by employees of CPRIT or by	Conflicts of Interest and improper awarding of grants	
Fraud Risk	those to whom CPRIT disburses funds	Inaccurate budgeting and forecasting	
	Consider the budgeting and planning, cash management, financia	Incorrect reporting to management and/or leadership offices	
	reporting requirements, non-conformance with ethical standards, etc.	Fraud by employees or employees of grantees	
		Policy is not properly created, documented or implemented	
		Processes are complex, not standardized, inefficient, or unsustainable	
	The risk that CPRIT's daily processes are not effectively designed to prevent and detect errors, or processes and their underlying	Silos and poor inter-departmental communication due to inadequate organizational structure	
Operations, Complexity and	mechanics introduce variances that may cause errors. Also includes the risks that internal processes rely on the knowledge	Committee meetings do not occur frequently or timely enough to provide adequate oversight	
Human Capital Risk	and expertise of individuals rather than processes, and the ability	Agency cannot respond to change rapidly enough	
	to find qualified employees with sufficient talent, ambition and training to operate effectively.	Inadequate employee skills and competence	
		Inadequate measurement of employee performance	
		Succession planning for key positions is not considered in staffing	
		Unstructured or ineffective IT Governance	
		Ineffective identification, adoption, implementation of new technology and the maintenance to support technology	
	The risk that CPRIT's IT strategy is not aligned with the business model to embrace and rely on technology. Also includes the risk that CPRIT is highly reliant on technology to execute strategic operations and that IT infrastructure and systems are not consistently available and reliable. Over-dependence and lack of management of third parties to provide processing support and access to CPRIT data. Consider availability of resources, data integrity, information security, recoverability of data, third-party reliance, etc.	Unauthorized access to secured data and systems	
	model to embrace and rely on technology Also includes the risk	Unmanaged internal information security or external security penetration	
		Unmanaged data integrity and reliability of internal/external data interchange	
rechnology Risk		Inappropriate data storage, management, and requirements	
	access to CPRIT data. Consider availability of resources, data	Ineffective IT support function	
		Data and systems unavailable or undependable	
		Ineffective implementation of system development life cycle	
		Dependence on third parties	
		Inadequate disaster recovery and business continuity plans	
		Competing philosophical differences	
Regulatory, Compliance and Public Policy Risk The risk that CPRIT's operations and ability to execute strategic goals will be impaired by regulatory and legislative action and changes outside CPRIT's control. Consider healthcare and research reform, and public policy changes.	Political pressures influence the awarding and monitoring of grant funds		
	The field and the control of the con	Shifts in public policy	
		Changes in funding structure between Texas State agencies	
		Turnover in the Oversight Committee	
	Regulatory changes are not monitored or are interpreted incorrectly		
		Financial reforms / new financial reporting standards	
		Damaged relationship with grant recipients	
		Board ineffectiveness or lack of expertise	
	reduced employee commitment. Relationships with and/or actions of grantees and other related parties reflect negatively on	Poor external perception of CPRIT	
eputational Risk	CPRIT. Increased state leadership oversight influencing the ongoing relevance of the organization and reducing the ability to	Actions of related parties reflect negatively on CPRIT	
		Poor management of external communication and information	
		Negative reports or information released in the public domain	

		Diek ratings should	mo 5 ou	Diek rations should be completed without considering controls in place to mitigate risk the participal or inherent risk for the activity
	Inherent Risk	Natural state of risk in an uncontrolled activity. The risk assessment is designed to evaluate the prevaluation of the inherent risk within each activity in	n an ur s design ent risk	Natural state of risk in an uncontrolled activity. The risk assessment is designed to evaluate the probability and impact of inherent risk in the identified activities, this requires each individual to put aside the existing controls so that a true evaluation of the inherent risk within each activity may be assessed.
				Elements of Risk to Consider
۵	Probability	The likelihood that the ris	k catego	The likelihood that the risk category intentionally or unintentionally influences the significant financial and operational activities of the organization.
	Impact- The impact	Impact	The ma	The magnitude of the influence that a risk category bears over the significant financial and operational activities of the organization.
-	composite of three factors:	Velocity	The spe	The speed at which the impact affects the organization after the occurrence of an influential event.
	Impact, Velocity and Persistence	Persistence	The dur	The duration of time of which influential events naturally occur within a risk category.
Score	Probability	Impact		Definition
	otomo C vec/		۵	A risk ranking of "low" for any specific areas indicates an event with an unlikely or remote probability in normal operations.
-	(<10% Chance)	Low	÷	A risk ranking of "low" for any specific area indicates an event that would have minimal impact on assets and strategic objectives of the organization. A "low" risk ranking should also consider and reflect the effect of an event would slowly impact the organization or that occasionally occurs.
			۵	A risk ranking of "below average" for any specific area indicates an event with a somewhat likely probability of occurrence in normal operations.
7	Somewhat Likely (>10% - <50% Chance)	Below Avg.		A risk ranking of "below average" for any specific area also indicates an event, which if to occur, would have a slightly moderate impact on assets and strategic objectives of the organization.
			-	A "below average" risk ranking should also consider and reflect the effect of the event would gradually impact the organization or would intermittently occur in normal operations.
			۵	A risk ranking of "moderate" for any specific area indicates an event with an average probability of occurrence in normal operations.
ო	Likely (>50% - <70% Chance)	Moderate	-	A risk ranking of "moderate" for any specific area also indicates an event, which if to occur, would have a noticeable, and possibly material, impact on assets and strategic objectives and
				A "moderate" risk ranking should also consider and reflect the effect of an event would quickly impact the organization, or periodically occur in normal operations,
			۵	A risk ranking of "above average" for any specific area indicates an event that is probable and/or likely to occur in normal operations.
4	Probable (>70% - <90% Chance)	Above Avg.	÷	A risk ranking of "above average" for any specific area also indicates and event, which if to occur, would have a material impact on assets and strategic objectives of the organization.
				An "above average" risk ranking should also reflect and consider that an event would rapidly impact the organization, and regularly exist in normal operations.
			۵.	A risk ranking of "high" for any specific area indicates and event with a very likely probability of occurrence in normal operations.
S.	Highly Probable (>90% Chance)	High	=	A risk ranking of "high" for any specific area also indicates an event, which if to occur, would have a significant material impact on assets and strategic objectives of the organization.
		T soul be store and account		A "high" risk ranking should also reflect that an event would immediately impact the organization and is an ongoing threat in normal operations.
11075	COUNTY HOLD HOLD ON THE CHILD IN THE COUNTY	1 1000	2000	ALCHING IN WHITE HIS GOOD SHOW THE WASHINGTON TO BE SHOWN FOR THE PARTY OF THE PART

Organizations have different tolerances for risk of loss. The risk categories included within this assessment are those which could significantly influence the institute and may prevent the organization from achieving its strategic objectives.

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I. Compliance with Texas Government Code, Section 2102.015: Posting the Internal Audit Plan, Internal Audit Annual Report, and Other Audit information on Internet Web site

Texas Government Code, Section 2102.015 requires state agencies and higher education institutions, as defined in the statue, to post their Internal Audit Plan, Internal Audit Annual Report, and other audit information on the Internet.

The Cancer Prevention and Research Institute of Texas (CPRIT or the agency) will post this report and its 2016 Internal Audit Plan on its website at www.cprit.state.tx.us following adoption by the Oversight Committee at its next quarterly meeting on November 19, 2015, and no later than December 1, 2015.

CPRIT will update its posting with a detailed summary of the weaknesses, deficiencies, wrongdoings or other concerns raised by performance of the audit plan as they are identified or by November 1, 2016. CPRIT will also update the posting with the corrective action taken to address any issues identified.

II. Compliance with the Benefits Proportionality Audit Requirements for Higher Education Institutions

On May 29, 2014, Governor Perry requested that internal auditors for higher education institutions conduct work to determine whether "proportionality is being applied according to the established guidelines." This requirement is not applicable to CPRIT.

III. Internal Audit Plan for Fiscal Year 2015

The internal audits planned and performed for Fiscal Year 2015 were selected to address the agency's highest risk areas, based on the risk assessment process conducted during the fall of 2013, which included input from CPRIT management. The audits conducted during fiscal year 2015 as listed below.

Internal Audit	Report #	Report Date	Current Status
Internal Audit over Grants Management	IA #01- 2015	July 27, 2015	The report was issued August 26, 2015. Follow-up procedures to verify that corrective action has been performed are included in the proposed 2016 Internal Audit Plan.
Internal Audit Follow-Up Over Prior Governance and Information Technology *	IA #02- 2015	August 14, 2015	The report was issued September 14, 2015. Follow-up procedures to verify that corrective action has been performed are included in the proposed 2016 Internal Audit Plan.
Internal Audit Follow-Up Over Prior Year Grantee Monitoring Audit Findings **	IA #03- 2015	July 31, 2015	The report was issued August 31, 2015. Follow-up procedures to verify that corrective action has been performed are included in the proposed 2016 Internal Audit Plan.
Internal Audit Over Expenditures	IA #04- 2015	August 24, 2015	The report was issued October 7, 2015. Follow-up procedures to verify that corrective action has been performed should be performed by management in fiscal year 2016.

- * The Audit Plan presented in the 2014 Internal Audit Annual Report included an internal audit over Information Technology. The scope of this audit was modified in 2015 to provide for the follow-up of findings identified in the previous Information Technology internal audit. Additionally, the scope was expanded to include follow-up of findings from the Governance internal audit.
- ** The Audit Plan presented in the 2014 Internal Audit Annual Report included Grantee Field Audits. During 2015, the Chief Compliance Officer implemented a grantee monitoring and compliance program. The responsibility to perform grantee field audits transitioned from Internal Audit to the Chief Compliance Officer. The scope of the Internal Audit Follow-Up Over Prior Year Grantee Monitoring Audit Findings was limited to grantees and findings that had been previously identified by Internal Audit in 2013 and 2014.

IV. Consulting Services and Nonaudit Services Completed

As defined in the Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing and the Government Auditing Standards, 2011 Revision, Sections 3.33 – 3.58, CPRIT completed the following consulting and non-audit services for FY 2015:

Internal Audit was outsourced to Grant Thornton until December 2014. Weaver was designated as the agency's Internal Auditor after the Legislative Budget Board approved the contract in April 2015. Weaver consulted with CPRIT to draft agreed upon procedures that detail the required audit steps to be completed for CPRIT grant recipients by an independent auditor to satisfy the State Single Audit requirements and CPRIT policies and procedures.

Other consulting and nonaudit services were provided by Grant Thornton and CohnReznick LLP. CPRIT engaged Grant Thornton as the third party to observe each in-person and telephone conference Peer Review Panel meeting and ensure compliance with conflict of interest and staff participation requirements. CohnReznick LLP was engaged by CPRIT to perform grant compliance monitoring services to ensure that CPRIT grant recipients are in compliance with Texas Uniform Grant Management Standards and CPRIT policies and procedures.

Grant Thornton issued the following reports during fiscal year 2015:

Grant Thornton FY2015 Third Party Observer Reports

Review Panel	Report #	Report Date	Status
FY 15 Scientific Review Council Meeting – Tenure Track Recruitment Applications	2014-28	October 1, 2014	Completed
Prevention Peer Review Panel	2014-29	October 2, 2014	Completed
Product Development Review Panel – 1 (ETRA)	2014-30	October 10, 2014	Completed
Product Development Review Panel – 2	2014-31	October 9, 2014	Completed
FY 15.2 Product Development Review Council	2015-05	October 21, 2014	Completed
Prevention Review Council	2015-206	October 24, 2014	Completed
Imaging Technology and Informatics	2015-207	October 27, 2014	Completed
Cancer Prevention Research	2015-208	November 17, 2014	Completed
Basic Cancer Research 2	2015-209	October 31, 2014	Completed
Cancer Biology	2015-210	November 3, 2014	Completed
Basic Cancer Research-1	2015-211	November 17, 2014	Completed
Translational Cancer Research & Clinical and Translational Cancer Research	2015-212	November 17, 2014	Completed
FY15 Scientific Review Council Meeting—Recruitment Program Applications	2015-213	January 7, 2015	Completed
FY15 Product Development Review Council	2015-214	January 8, 2015	Completed
FY15 Prevention Peer Review 1	2015-215	February 25, 2015	Completed
FY15 Prevention Peer Review Panel 2	2015-216	February 25, 2015	Completed
FY15 Basic Cancer Research-1	2015-217	March 10, 2015	Completed
FY 15.2 Cancer Biology	2015-218	March 13, 2015	Completed
FY15.2 Imaging Technology and Informatics	2015-219	March 13, 2015	Completed



Review Panel	Report #	Report Date	Status
FY15.2 Clinical & Translational Cancer Research and Translational Cancer Research	2015-220	March 23, 2015	Completed
FY15.2 Cancer Prevention Research	2015-221	March 23, 2015	Completed
FY15.2 Basic Cancer Research – 2	2015-222	March 23, 2015	Completed
FY15.2 Recruitment Review Panel (RRP-5 and RRP-6)	2015-223	March 27, 2015	Completed
FY15.4 Product Development Panel-1	2015-224	March 30, 2015	Completed
FY15.2 Recruitment Review Panel – 7 & FY15.2 Scientific Research Applications	2015-225	April 13, 2015	Completed
FY15.1 Due Diligence Evaluation Meeting—2	2015-226	April 22, 2015	Completed
FY15.2 Prevention Review Council Programmatic Review	2015-227	April 22, 2015	Completed
FY15.4 Product Development Panel – 1	2015-228	April 28, 2015	Completed
FY15.2 Recruitment Review Panel—8	2015-229	May 21, 2015	Completed
FY15,2 Recruitment Review Panel—9	2015-230	June 12, 2015	Completed
FY15.2 Recruitment Review Panel—10	2015-231	July 16, 2015	Completed
FY16.1 Recruitment Review Panel	2015-232	August 16, 2015	Completed

CohnReznick issued the following reports during fiscal year 2015:

CohnReznick FY2015 Grant Compliance Monitoring Reports

Report Name	Report #	Report Date	Current Status
Beta Cat Pharmaceuticals, LLC	GMR- CP130058.201506	August 11, 2015	Completed. No Findings Identified
Texas A&M Engineering Experiment Station	GMR- RP150421.201506	August 11, 2015	Completed. No Findings Identified
Texas A&M University	GMR- RP121002.201506	August 11, 2015	Completed. No Findings Identified
Asuragen, Inc.	GMR- CP120017.201507	August 11, 2015	Completed. No Findings Identified
Kalon Biotherapeutics, LLC	GMR- CP120038.201507	August 11, 2015	Completed. No Findings Identified
The University of North Texas Health Science Center at Fort Worth	GMR- DP150091,201507	August 11, 2015	Completed. No Findings Identified
Scott and White Healthcare	GMR- RP140678.201507	August 11, 2015	Completed. No Findings Identified
Texas Tech University Health Science Center at El Paso	GMR- PP140164.201507	August 11, 2015	Completed. No Findings Identified
The University of Texas Southwestern Medical Center	GMR- DP150056.201507	August 11, 2015	Completed. No Findings Identified
The University of Texas at Austin	GMR- RP140108.201506	August 12, 2015	Completed. No Findings Identified
Molecular Templates, Inc.	GMR- CC121020.201506	August 12, 2015	Completed. No Findings Identified
Texas Tech University Health Science Center at Dallas	GMR- RP120495.201507	August 12, 2015	Completed. No Findings Identified
Texas Tech University	GMR- RP130624.201507	August 12, 2015	Completed. No Findings Identified
The University of Texas Health Science Center at Houston	GMR- RP140103.201506	August 13, 2015	Completed. No Findings Identified
Baylor University	GMR- R1309.201506	August 13, 2015	Two findings identified. Remediation testing will occur in FY 2016
The Rose	GMR- PP120040.201507	August 13, 2015	Completed. No Findings Identified
The University of Texas Medical Branch at Galveston	GMR-RP140020- C1.201507	August 13, 2015	Completed. No Findings Identified

Report Name	Report #	Report Date	Current Status
Baylor College of Medicine	GMR- DP150064.201507	August 13, 2015	Completed. No Findings Identified
ESSA Pharma Inc.	GMR- CP130020.201507	August 13, 2015	Completed. No Findings Identified
The University of Texas Southwestern Medical Center	GMR- R1109.201506	August 19, 2015	One finding identified. Remediation testing will occur in FY 2016
Baylor Research Institute	GMR-RP110553- P5.201506	August 19, 2015	Completed. No Findings Identified
The University of Texas M.D. Anderson Cancer Center	GMR- DP150094.201507	August 19, 2015	Completed. No Findings Identified
Texas Agrilife Extension Service	GMR- PP120099.201508	August 19, 2015	Completed, No Findings Identified
Rice University	GMR-RP140024- P1.201506	August 20, 2015	Completed. No Findings Identified
The University of Texas Health Science Center at Houston	GMR- DP150093.201507	August 20, 2015	Completed. No Findings Identified
DNAtrix, Inc.	GMR- CP130013.201507	August 20, 2015	Completed. No Findings Identified
The University of Texas at Austin	GMR- DP150061.201507	August 20, 2015	Completed. No Findings Identified
University of Houston	GMR- RP140113.201508	August 20, 2015	Completed. No Findings Identified
Baylor College of Medicine	GMR- RR140033.201508	August 20, 2015	Completed. No Findings Identified
Centro San Vicente	GMR- PP120059.201507	September 4, 2015	Completed. No Findings Identified
Texas A&M University Health Science Center Institute of Biosciences and Technology	GMR-RP110532- P2.201507	September 4, 2015	Completed. No Findings Identified
Texas Tech University Health Sciences Center	GMR- RR140008.201508	September 10, 2015	One finding identified. Remediation testing will occur in FY 2016
The University of Texas Health Science Center at San Antonio	GMR- DP150055.201508	September 10, 2015	Completed. No Findings Identified
The University of Texas Health Science Center at San Antonio	GMR- RP140105.201508	September 10, 2015	Completed. No Findings Identified
The Bridge Breast Network	GMR- PP140026.201508	September 10, 2015	Completed. No Findings Identified
The University of Texas at El Paso	GMR-RP110444- P2.201508	September 11, 2015	Completed. No Findings Identified
Pulmotect, Inc.	GMR- CP120014.201508	September 11, 2015	Completed. No Findings Identified
The University of Texas Health Science Center at Houston	GMR- PP130075.201508	September 14, 2015	Completed. No Findings Identified
The University of Texas at San Antonio	GMR- PP140209.201508	September 15, 2015	Completed. No Findings Identified
The University of Texas Health Center at Tyler	GMR- PP140018.201508	September 15, 2015	Completed. No Findings Identified
The Methodist Hospital Research Institute	GMR- RP121071.201508	September 15, 2015	One finding identified. Remediation testing will occur in FY 2016
The University of Texas M.D. Anderson Cancer Center	GMR- RP130397.201508	September 15, 2015	Completed. No Findings Identified
The University of Texas Southwestern Medical Center	GMR- R1119.201508	September 15, 2015	Completed. No Findings Identified
The University of Texas Southwestern Medical Center	GMR- R1121.201508	September 15, 2015	Completed. No Findings Identified

Report Name	Report #	Report Date	Current Status
The University of Texas Medical Branch at Galveston	GMR- PP120150.201508	September 15, 2015	Completed. No Findings Identified
Rice University	GMR- R1226.201508	September 15, 2015	Completed. No Findings Identified
The University of Texas Southwestern Medical Center	GMR- PP120229.201508	September 15, 2015	Completed. No Findings Identified
CerRx, Inc.	GMR- CP130023.201508	September 15, 2015	Completed. No Findings Identified
Cancer and Chronic Disease Consortium	GMR- PP120211.201508	September 15, 2015	Completed. No Findings Identified
Legacy Community Health Services	GMR- PP140208.201508	September 15, 2015	Completed. No Findings Identified
The University of Texas Southwestern Medical Center	GMR- RP130166.201508	September 15, 2015	Two findings identified. Remediation testing will occur in FY 2016
Texas Agrilife Research	GMR- RP130639.201508	October 1, 2015	One finding identified. Remediation testing will occur in FY 2016
Angelo State University	GMR- PP120108.201508	October 7, 2015	Completed. No Findings Identified
The University of Texas Southwestern Medical Center	GMR- PP120097.201508	October 7, 2015	Completed. No Findings Identified
University Health System	GMR- PP120111.201508	October 7, 2015	Completed. No Findings Identified

V. External Quality Assurance Review

In accordance with professional standards, and to meet the requirements of the Texas Internal Auditing Act, Internal Audit is required to undergo an external quality assurance review at least once every three years. Weaver's review was performed in October 2013.



System Review Report

October 4, 2013

To the Partners of Weaver and Tidwell, L.L.P. and the National Peer Review Committee

We have reviewed the system of quality control for the accounting and auditing practice of Weave and Tidwell, L.L.P. (the firm) applicable to non-SEC issuers in effect for the year ended May 31, 2013. Our peer review was conducted in accordance with the Standards for Performing and Reporting on Peer Reviews established by the Peer Review Board of the American Institute of Certified Public Accountants. As a part of our peer review, we considered reviews by regulatory entities, if applicable, in determining the nature and extent of our procedures. The firm is responsible for designing a system of quality control and complying with it to provide the firm with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Our responsibility is to express an opinion on the design of the system of quality control and the firm's compliance therewith based on our review. The nature, objectives, scope, limitations of, and the procedures performed in a System Review are described in the standards at www.nicpa.org/prsummary.

As required by the standards, engagements selected for review included engagements performed under Government Auditing Standards, audits of employee benefit plans, audits performed under FDICIA, and examinations of service organizations (Service Organizations Control (SOC) 1 and 2 engagements).

In our opinion, the system of quality control for the accounting and auditing practice of Weaver and Tidwell, L.L.P. applicable to non-SEC issuers in effect for the year ended May 31, 2013, has been suitably designed and complied with to provide the firm with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Firms can receive a rating of pass, pass with deficiency (ies) or fail. Weaver and Tidwell, L.L.P. has received a peer review rating of pass.

Eide Bailly LLP

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VI. Internal Audit Plan

The 2016 Internal Audit Plan has not been approved by the Audit Subcommittee of CPRIT's Oversight Committee. The Internal Audit Plan has been submitted to the Audit Subcommittee and is anticipated to be approved on November 6, 2015. Below is the 2016 Internal Audit Plan submitted to the agency's Oversight Committee for approval based on the results of the 2015 Internal Audit Risk Assessment. The approved internal audit plan will be submitted to the State Auditor's Office by December 1, 2015.

Fiscal Year 2016 Internal Audit Plan		
Audit Area	2015 Risk Rating	Estimated Hours
Information Security	High	260-300
Commodity and Service Contracts	High	220-225
Revenue	Moderate	270-300
Cash Management	Moderate	230-250

Planned follow-up procedures for fiscal year 2016 to verify and communicate with Management the remediation efforts of prior Internal Audit Recommendations.

Fiscal Year 2016 Follow-up Procedures		
Audit Area	2015 Risk Rating	Estimated Hours
Pre-Award Grant Management Post Award Grand Management Grant Contracting	High	150-180
Information Technology Services	Moderate	60-80

Senate Bill 20 (84th Legislature) requires considering performance of audits on contracts entered into by the Health and Human Services Commission that exceed \$100 million in annual value.

The 2015 Internal Audit Risk Assessment resulted in six Significant Activities rated as "High" risk. Two of the six Significant Activities are not included in the fiscal year 2016 Internal Audit Plan. Those risks are as follows:

- 1. **Procurement** Procurement was not included in the 2016 Internal Audit Plan. Procurement was included in the 2013 and 2014 Internal Audit Plans. Upon approval by the Oversight Committee, procurement is also anticipated to be included in the 2017 Internal Audit Plan.
- 2. Governance Governance was not included in the 2016 Internal Audit Plan. Governance was included in the 2014 Internal Audit Plan, and was included in 2015 follow-up procedures.

VII. External Audit Services Procured in FY 2015

CPRIT engaged McConnell & Jones, LLP, a certified public accounting and consulting firm, as their external auditors for FY 2015. McConnell & Jones, LLP is registered with the Public Company Auditor Oversight Board (PCAOB).

VIII. Reporting Suspected Fraud, Waste and Abuse

- CPRIT contracts with Red Flag Reporting to provide a confidential hotline for reporting fraud, waste and abuse. The agency has posted a link on its home page at www.cprit.state.tx.us and also has a dedicated page to fraud prevention and reporting on its website at http://www.cprit.state.tx.us/about-cprit/fraud-prevention/.
- The CPRIT Chief Compliance Officer is the designated staff member within the agency to receive
 written or verbal allegations of suspected fraud, waste, and abuse. The Chief Compliance Officer
 has the authority to examine and investigate those allegations and turn over information of
 verified instances of fraud, waste, or abuse to the State Auditor's Office.



MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: WAYNE ROBERTS, CEO, REBECCA GARCIA, PHD, CHIEF

PREVENTION AND COMMUNICATIONS OFFICER

SUBJECT: 2016 PROGRAM PRIORITIES

DATE: DATE

Recommendation:

That the Oversight Committee adopt the 2016 program priorities as recommended by the Oversight Committee program subcommittees.

Background:

The Oversight Committee approved the 2015 program priorities on November 19, 2014 after a six month process that included subcommittee meetings and public input. The program priorities were subsequently incorporated into the requests for applications released by each program. In August 2015, the Academic Research, Product Development Research and Prevention Oversight Committee Subcommittees reviewed the 2015 program priorities and determined that no changes to the priorities were needed for 2016. The attached report includes minor updates to introductory paragraphs but no changes to the priorities.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS PROGRAM PRIORITIES FOR 2016

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ABOUT CPRIT PROGRAM PRIORITIES PROJECT

CPRIT is governed by Health and Safety Code: Chapter 102. Legislation from the 83rd Texas Legislature modified that code to include enhancements to CPRIT's governance and operations. One of the specific enhancements requires CPRIT's Oversight Committee to establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio between and within its three programs as well as guide CPRIT staff and Review Councils on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

The Oversight Committee priorities are to be reviewed and adjusted annually as circumstances change and new information is found concerning cancer-related advances in prevention, academic research and product development research

CPRIT Purpose

Health and Safety Code: Chapter 102

Sec. 102.002. PURPOSES. The Cancer Prevention and Research Institute of Texas is established to:

- (1) create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;
- (2) attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this state; and
- (3) develop and implement the Texas Cancer Plan.

Program Priorities Legislative Mandate

Health and Safety Code: Chapter 102

Sec. 102.107. POWERS AND DUTIES. The oversight committee shall:

- (1) hire a chief executive officer;
- (2) annually set priorities as prescribed by the legislature for each grant program that receives money under this chapter; and
- (3) consider the priorities set under Subdivision (2) in awarding grants under this chapter.



PROCESS TO DEVELOP PROGRAM PRIORITIES

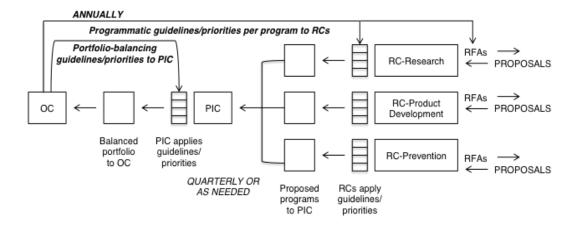
The Oversight Committee approved the 2015 program priorities on November 19, 2014 after a six month process that included subcommittee meetings and public input. The program priorities were subsequently incorporated into the requests for applications released by each program. In August 2015, the Academic Research, Product Development Research and Prevention Oversight Committee Subcommittees reviewed the 2015 program priorities and determined that no changes to the priorities were needed for 2016. Their recommendations were presented at the Oversight Committee meeting on November 19, 2015.

SCOPE OF PROGRAM PRIORITIES PROJECT

The Program Priorities Project establishes priorities at two levels of CPRIT's grant making process:

- **Priorities Within Each of CPRIT's Programs** priorities to inform staff and respective Peer Review Councils (RCs) on the development and issuance of program-specific Requests for Applications (RFAs) and evaluation of applications submitted in response to those RFAs.
- Priorities Across CPRIT's Three Programs priorities to inform the Program Integration Committee
 (PIC) on balancing the portfolio across the research, prevention and product development programs.

Priorities and CPRIT's Grant Making Process





CPRIT'S LONG-TERM VISION

As the Oversight Committee set out to establish program priorities, it began by defining the long-term vision for the agency and each of the three programs in alignment with CPRIT's mandated purpose.

Innovative projects funded by CPRIT will result in:

- A decrease in the burden of cancer in Texas through preventive measures, new diagnostics and treatments, and effective translation of discoveries into products;
- A recognition of and focus on disparities in cancer incidence, mortality and access to care;
- Significant advancements in the scientific understanding of cancer; and
- An enhanced and expanded life sciences infrastructure in the state as a result of recruiting researchers,
 training health care/science professionals, attracting companies and supporting investigator startups.

PRIORITIES WITHIN EACH OF CPRIT'S PROGRAMS

Priorities within each of CPRIT's programs –academic research, prevention and product development research—will inform staff and respective Peer Review Councils on the development and issuance of program-specific Requests for Applications (RFAs) and evaluation of applications to those RFAs.

CPRIT's three programs are currently guided by established key principles essential to executing CPRIT's purpose. The main principle underlying all three programs is that they will continue to ensure only applications with scientific merit will move forward in CPRIT's peer review grant process. In addition, the programs have established principles that are unique to each program. The new program priorities will supplement these principles to guide the selection of meritorious applications to address CPRIT's strategic priorities as set annually by the Oversight Committee.

It is important to note that these priorities do not exclude funding in areas outside of the identified priorities.

Academic Research Program

Background:

The goal of CPRIT's academic research program is to discover new information about cancer that can lead to prevention, early detection, and more effective treatments; translate new and existing discoveries into practical advances in cancer diagnosis, treatment, and survivorship; and increase the prominence and stature of Texas in the fight against cancer. Until now, CPRIT's strategy has been to support the most creative ideas and the most meritorious projects brought forward by the cancer research community in Texas. Going forward, the overarching principles for awarding CPRIT funds will continue to be scientific excellence and impact on reducing the burden of cancer. However, more strategic deployment of funds is



intended to accelerate progress in cancer research beyond what can be achieved by simply adding incrementally to the types of cancer research funded by other agencies.

Therefore, CPRIT's academic research program will seek to fund projects in critical, but underfunded areas of cancer research, in addition to funding investigator-initiated, untargeted proposals. Areas of opportunity for strategic deployment of funds include prevention and early detection research; computational biology and analytic methods; rare cancers, particularly pediatric tumors, and intractable cancers, including lung, liver, pancreatic and brain cancers, with particular emphasis on population disparities and cancers of significance in Texas

Finally, it is critically important to add to the life sciences infrastructure in the State of Texas. This will enable CPRIT's impact on cancer research to extend for years beyond the lifetime of the program. Most important to increasing infrastructure is the recruitment of preeminent researchers. Such individuals bring additional resources to the State, including research funding and new expertise, as well as help build the critical mass of science needed to attract investments in the development of products for cancer prevention, diagnosis, and treatment. Also critical are the training programs that aim to produce the next generation of cancer researchers and increase the diversity of the cancer research workforce.

Established Principles:

- o Scientific excellence and impact on cancer
- o Targeting underfunded areas
- o Increasing the life sciences infrastructure

Academic Research Program Priorities

- A broad range of innovative, investigator-initiated research projects
- Prevention and early detection
- Computational biology and analytic methods
- Rare and intractable cancers, including childhood cancers
- Population disparities and cancers of importance in Texas
- Recruit outstanding cancer researchers to Texas



Prevention Program

Background:

The following principles have guided the prevention program since its inception in 2009. These principles have informed the development of the requests for applications (RFAs) and the evaluation of applications submitted in response to the RFAs.

Through the prevention program, CPRIT seeks to fund projects that:

- Are evidence based offering effective prevention interventions based on the existing body of knowledge about and evidence for cancer prevention.
- Deliver primary, secondary, or tertiary (includes survivorship) prevention interventions – providing state of the art preventive clinical services and tailored, culturally appropriate, and accurate information to the public and health professionals.

In addition, the program has focused on providing access to underserved populations and serving the populations in most need including underinsured and uninsured individuals and those disproportionately affected by cancer.

In order to achieve some degree of balance to the prevention program portfolio, the Prevention Review Council (PRC) conducts a programmatic review of applications under consideration. During programmatic review, the Prevention Review Council (PRC) evaluates applications judged to be meritorious by prevention review panels. Programmatic considerations include:

- Potential for impact
- Geographic distribution
- Cancer type
- Type of program or service

While these principles provide guidance for the program, identifying priorities based on areas where significant cancer incidence and mortality disparities exist focuses the program further on areas of greatest need and greatest potential for impact.

Data on cancer incidence, mortality and disparities (geographic, ethnic, etc.) are reviewed annually to identify priorities and identify areas of emphasis. This information informs the development of RFAs and informs programmatic decisions during the PRC level of review.



Established Principles:

- o Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary and tertiary (includes survivorship) prevention interventions

Prevention Program Priorities

- Prioritize populations and geographic areas of greatest need, greatest potential for impact
- Focus on underserved populations
- Increase targeting of preventive efforts to areas where significant disparities in cancer incidence or mortality in the state exist

Product Development Research

Background: CPRIT's product development program should:

- Identify private sector entities to develop products that will benefit cancer patients –
 Gaps exist in the market's ability to translate research insights and product visions into
 FDA approved and commercially available products. These gaps may delay, or even
 deny, cancer patient access to important scientific advances. CPRIT should work to
 bridge these gaps, leveraging its funds with matching funds from other sources.
- Selectively deploy its resources where they are most needed and can do the most good There are more scientifically and commercially sound product development opportunities than CPRIT is capable of funding. Thus, CPRIT should:
 - o Fund commercial projects that might be "game changing" or disruptive;
 - Attract and support cancer-related life sciences companies that will create jobs in Texas;
 - o Attract matching funds and additional investments from other sources; and
 - Act in conjunction, but not in competition, with private funding sources or other governmental funding sources.



Established Principles:

- Moving forward the development of commercial products to diagnose and treat cancer and improve the lives of cancer patients
- o Creation of good, high-paying jobs for Texans
- o Sound financial return on the monies invested
- o Development of the Texas high tech life sciences business environment

Product Development Research Program Priorities

- Funding projects at Texas companies and relocating companies that are most likely to bring important products to the market
- Providing funding that promotes the translation of research at Texas institutions into new companies able to compete in the marketplace
- Identifying and funding projects to develop tools and technologies of special relevance to cancer research, treatment, and prevention

PRIORITIES ACROSS CPRIT'S THREE PROGRAMS

Establishing priorities across CPRIT's research, prevention and product development programs will inform the Program Integration Committee (PIC) on balancing the portfolio across the three programs.

CPRIT's structure, which includes programs in research, prevention and product development, presents a unique opportunity for funding projects that span the continuum from discovery to delivery to the public and creating synergy across the spectrum. While CPRIT programs would continue to fund a broad range of programs and cancer types, selecting areas of emphasis where CPRIT could have an impact and distinguish it from other funding sources provides a basis for focusing resources and guiding decisions when resources are limited. The recommended areas of emphasis outlined below also correspond to unmet needs – places in the cancer research and care continuum where existing institutions have not provided strong programs or results.

It is important to note that these priorities serve as strategic areas of emphasis and do not exclude funding in areas outside of the identified priorities.



Prevention and Early Detection Initiatives

Nowhere is there greater potential to reduce the burden of cancer than by reducing its incidence. This spares people and families from the psychological and emotional trauma of a cancer diagnosis, the often devastating physical consequences of cancer therapies, and the financial burden associated with cancer treatment. In addition, the current emphasis in cancer research on finding cures for advanced cancers has serious limitations. Thus far, attempts to control cancer by chemotherapy, radiation, and even targeted therapy have been thwarted by the ability of cancer cells to develop resistance to these treatment modalities. Detecting cancer early in its development is a more desirable approach to cancer control. In spite of the potential impact of prevention and early detection on reducing the cancer burden, these areas of cancer research receive little funding relative to funding devoted to curing advanced cancer.

Emphasis: Ideally, academic research would create the evidence base for new approaches to prevention and early detection, product development research would provide new methods, diagnostics, imaging or devices for early cancer detection, and the prevention program would implement interventions to put these new approaches into practice once a solid evidence base of effectiveness exists. Strategies would include each program issuing either a targeted RFA or listing prevention or early detection as an area of emphasis (among others) within current RFAs. In addition, the programs can explore RFAs that could span programs, e.g. RFAs that would support a research component to a prevention project.

Early Translational Research

Rationale: One well-documented impediment to bringing the results of basic research to bear on cancer is the shortage of funding to translate new discoveries into practical advances for cancer patients. Research and development are needed between the stages of discovery science, traditionally funded by grants from federal sources and foundations, and late term development and commercialization of drugs, devices, diagnostic tests, and biologicals traditionally funded by private sector industries. Data indicate that such translational research is underfunded and would benefit from additional investment. Funding such research and development by CPRIT could have the added benefit of stimulating public-private partnerships and bringing new commercial investments to Texas.

Emphasis: Funding translational research that bridges the gap between basic research and product development, and between research on preventive measures and new technologies for early detection and on adaptation of tested interventions represents opportunities for inter-program strategic investment by CPRIT. The time needed to move some projects from research to products is often lengthy and may limit the role of the prevention program in this area of emphasis.



Enhance Texas' Research Capacity and Life Science Infrastructure

Rationale: CPRIT's statute emphasizes enhancing research superiority, increasing applied science and technology research capabilities and increasing high-quality jobs in the state. All three programs contribute to enhancing the research, life science and cancer control workforce and infrastructure in the state.

Emphasis: Establishing a critical mass of cancer researchers in Texas is possible by supporting the recruitment of cancer scientists and clinicians, at all career levels, to academic institutions in Texas and through training programs in which pre- and post-doctoral fellows are educated to become cancer researchers. The recruitment program has been successful in enhancing Texas' cancer research efforts and increasing the external visibility of the state in the medical and scientific communities.

> CPRIT's investments in product development help to build Texas' life-science industry. While bringing a product to market can take time, jobs and economic activity are generated throughout the process. Every CPRIT award includes intellectual property requirements that specify a revenue return to Texas through the successful development of CPRIT-funded drugs, devices, diagnostics or services.

The prevention program supports the education and training of health care professionals and community workers, thereby increasing the state's capacity for cancer prevention and control activities. By requiring collaborative partnerships, the program also creates incentives for organizations and individuals to collaborate to tackle community problems through networks that can mobilize resources and avoid duplication of efforts. Implementing system changes (such as reducing wait times between screening and diagnostics, implementing patient reminder systems) by CPRIT funded programs also improves the infrastructure for the delivery of preventive interventions.



Summary: Priorities across CPRIT's Three Programs

Below is a table summarizing how each of CPRIT's three programs would implement the recommended areas of emphasis outlined above.

Academic Research Program Implementation	Prevention and Early Detection Initiatives Create the evidence base for new approaches to prevention and early detection.	Early Translational Research Identify CPRIT funded basic research that could translate new discoveries into practical advances.	Enhance Texas' Research Capacity and Life Science Infrastructure Increase workforce and infrastructure: researcher recruitment, training grants and core facilities.
Prevention Program Implementation	Implement programs to put these new approaches into practice and continue to fund what is known to work (evidence based).	Due to long lead-time to product development, there may be limited role for prevention to implement programs resulting from this research.	Implementing systems change, developing partnerships and collaborations, training of community and healthcare providers, and creating new jobs.
Product Development Research Program Implementation	Fund new tools, technologies, methods and devices for early cancer detection and prevention.	Fund translational research that bridges the gap between basic research and product development.	Build up life sciences infrastructure and industry in Texas and create new high paying jobs.



MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS

From: NED HOLMES, CHAIR BOARD GOVERNANCE SUBCOMMITTEE

Subject: INTENTION TO RECOMMEND APPROVAL OF PROPOSED

CHANGE TO CPRIT BYLAWS

Date: NOVEMBER 4, 2015

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee approve the proposed change to Section 6.3 of the Oversight Committee Bylaws. The Board Governance Subcommittee discussed the proposed amendments with CPRIT's General Counsel at its meeting on November 4, 2015.

Discussion

The proposed change to Section 6.3 of the Oversight Committee Bylaws clarifies that the Chief Executive Officer has contract execution authority, subject to approval by the Oversight Committee and specific delegation when necessary. In addition, the change authorizes the Chief Operations Officer to execute contracts, including grant award contracts, in the absence of the CEO, pursuant to the CEO's prior notification to the Oversight Committee.

The Board Governance Subcommittee has reviewed the proposed amendment and recommends that the Oversight Committee approve the change.



THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

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CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS OVERSIGHT COMMITTEE BYLAWS

ARTICLE 1 ESTABLISHMENT AND PURPOSES

Section 1.1 Establishment. The Cancer Prevention and Research Institute of Texas (the "<u>Institute</u>") was established by the Texas Legislature in 2007, as authorized by Article 3, Section 67 of the Constitution of the State of Texas. The statutory provisions establishing the Institute are set forth in Chapter 102 of the Health and Safety Code of the State of Texas (the "<u>Health and Safety Code</u>"). Administrative rules governing the Institute are set forth in Title 25, Chapters 701–704, of the Texas Administrative Code.

Section 1.2 Purposes. The Institute is established to:

- (a) create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;
- (b) attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this state; and
 - (c) develop and implement the Texas Cancer Plan.

ARTICLE 2 AUTHORITY, AMENDMENT, AND INTERPRETATION

- Section 2.1 <u>Rulemaking Authority</u>. These Bylaws ("<u>Bylaws</u>") have been adopted by the Oversight Committee (as defined herein) pursuant to the authority granted to the Oversight Committee in Section 102.108 of the Health and Safety Code.
- Section 2.2 <u>Amendment</u>. These Bylaws may be amended or modified only with the approval of a simple majority of the members of the Oversight Committee as set forth in Section 3.13; <u>provided</u>, that no amendment or modification to these Bylaws may be made if such amendment or modification would cause these Bylaws to conflict with applicable law. All approved amendments or modifications shall be noted in a "Statement of Revisions" at the end of these Bylaws.
- Section 2.3 <u>Interpretation</u>. These Bylaws are adopted subject to any applicable law, including, but not limited to, Chapter 102 of the Health and Safety Code and Title 25, Chapters 701–704, of the Texas Administrative Code. Whenever these Bylaws may conflict with applicable law, the conflict will be resolved in favor of the applicable law. If at any time the Oversight Committee determines that these Bylaws conflict with

applicable law, then the Oversight Committee shall promptly act to amend these Bylaws to cause them to conform to applicable law.

ARTICLE 3 THE OVERSIGHT COMMITTEE

- Section 3.1 <u>General Powers</u>. The Oversight Committee of the Institute (the "<u>Oversight Committee</u>") is the governing body of the Institute. The Oversight Committee may adopt such policies and practices, consistent with applicable law, as it may deem proper for the conduct of its meetings and the management of the Institute.
- Section 3.2 <u>Number</u>. The Oversight Committee is composed of the following nine (9) members:
 - (a) three members appointed by the Governor of the State of Texas;
- (b) three members appointed by the Lieutenant Governor of the State of Texas; and
- (c) three members appointed by the Speaker of the House of Representatives of the State of Texas

Section 3.3 Composition; Disqualification.

- (a) The members of the Oversight Committee must represent the geographic and cultural diversity of the State of Texas. In making appointments to the Oversight Committee, the Governor, Lieutenant Governor, and Speaker of the House of Representatives of the State of Texas shall each appoint at least one person who is a physician or a scientist with extensive experience in the field of oncology or public health and should attempt to include cancer survivors and family members of cancer patients if possible.
- (b) A person may not be a member of the Oversight Committee if the person or the person's spouse: (i) is employed by or participates in the management of a business entity or other organization receiving money from the Institute; (ii) owns or controls, directly or indirectly, an interest in a business entity or other organization receiving money from the Institute; or (iii) uses or receives a substantial amount of tangible goods, services, or money from the Institute, other than reimbursement authorized by law for Oversight Committee membership, attendance, or expenses.
 - Section 3.4 <u>Term.</u> Each member of the Oversight Committee will hold office for such member's term or until such member's earlier death, resignation, disqualification, or removal. Members of the Oversight Committee appointed by the Governor, Lieutenant Governor, and Speaker of the House of Representatives of the State of Texas serve at the pleasure of the appointing office for staggered six-year terms, with the terms of three members expiring on January 31 of each odd-numbered year. Not later than the 30th day after the date an Oversight Committee member's term expires, the appropriate appointing authority shall appoint a replacement.

- Section 3.5 <u>Vacancy</u>. If a vacancy occurs on the Oversight Committee, then the appropriate appointing authority shall appoint a successor, in the same manner as the original appointment, to serve for the remainder of the unexpired term. The appropriate appointing authority shall appoint the successor not later than the 30th day after the date the vacancy occurs.
- Section 3.6 <u>Resignation</u>. Any appointed or designated member of the Oversight Committee may resign at any time by notice given in writing to the appropriate appointing authority and to the Chair of the Oversight Committee or to the Vice Chair if the Chairman is resigning. The resigning member will continue to serve until such time that the appropriate appointing authority appoints a successor.
- Section 3.7 Removal. It is a ground for removal from the Oversight Committee that a member: (a) is ineligible for membership of the Oversight Committee under Section 3.3(b) of these Bylaws; (b) cannot, because of illness or disability, discharge the member's duties for a substantial part of the member's term; or (c) is absent from more than half of the regularly scheduled Oversight Committee meetings that the member is eligible to attend during a calendar year without an excuse approved by a majority vote of the Oversight Committee. If the Chief Executive Officer has knowledge that a potential ground for removal exists, then the Chief Executive Officer shall notify the Chairperson of the potential ground. The Chairperson shall then notify the appointing authority and the Attorney General of the State of Texas that a potential ground for removal exists. If the potential ground for removal involves the Chairperson, then the Chief Executive Officer shall notify the next highest ranking officer of the Oversight Committee, who shall then notify the appointing authority and the Attorney General of the State of Texas that a potential ground for removal exists. Notwithstanding, the foregoing, the validity of an action of the Oversight Committee is not affected by the fact that it is taken when a ground for removal of a committee member exists.
- Section 3.8 <u>Strategic Partnerships</u>. To the fullest extent permitted by applicable law, the Oversight Committee retains the authority and power to approve strategic partnerships, alliances, and coalitions of the Institute subject to vote of the simple majority of the members of the Oversight Committee as set forth in Section 3.13.
- Section 3.9 <u>Regular Meetings</u>. The Oversight Committee shall hold a public meeting at least once in each quarter of the calendar year, with appropriate notice and with a formal public comment period.
- Section 3.10 <u>Special Meetings</u>. Special meetings of the Oversight Committee may be held upon the call of the Chairperson of the Oversight Committee, or the Vice Chairperson of the Oversight Committee when performing the duties of the Chairperson, as he or she may deem necessary, with appropriate notice and with a formal public comment period. Emergency meetings and telephonic meetings may be held only as provided under applicable law.
- Section 3.11 <u>Notice of Open Meetings</u>. All meetings of the Oversight Committee are subject to the terms of the Open Meetings Act, Chapter 551 of the Texas Government Code (the "<u>Open Meetings Act</u>"). The Open Meetings Act provides that the public must

be given notice of the time, place, and subject matter of meetings of governmental bodies. In absence of an emergency, notice of a meeting must be posted at a place that is readily accessible to the public at all times at least seven (7) days preceding the scheduled time of the meeting. In case of an emergency of urgent public necessity, which shall be clearly identified in the notice, it shall be sufficient if the notice is posted two hours before the meeting is convened.

Section 3.12 Quorum. The presence of a simple majority of the members of the Oversight Committee present is necessary and sufficient to constitute a quorum for the transaction of business at any meeting of the Oversight Committee.

Section 3.13 <u>Action By Simple Majority Vote</u>. Except as otherwise provided by these Bylaws or applicable law, the vote of a simple majority of the members of the Oversight Committee present at a meeting at which a quorum is present will be the prevailing action of the Oversight Committee.

Section 3.14 <u>Expenses</u>. A member of the Oversight Committee is not entitled to compensation, but is entitled to reimbursement for actual and necessary expenses incurred in attending meetings of the Oversight Committee or performing other official duties authorized by the Chairperson.

Section 3.15 <u>Training</u>. The Institute's General Counsel and Chief Compliance Officer shall provide training to all new members of the Oversight Committee and shall provide ongoing or continuing training to all members of the Oversight Committee not less than once a year. The form and substance of such training will be in the discretion of the Institute's General Counsel and Chief Compliance Officer. Each new member of the Oversight Committee shall also complete a course of training regarding his or her responsibilities under the Open Meetings Act within 90 days of becoming a member of the Oversight Committee.

ARTICLE 4 SUBCOMMITTEES OF THE OVERSIGHT COMMITTEE

Generally. The Oversight Committee may designate one or more Section 4.1 subcommittees of the Oversight Committee, each subcommittee to consist of three or more of the members of the Oversight Committee. The Oversight Committee shall appoint and approve members of the subcommittees specifically listed in Section 4.2, except for the members of the Executive Committee, which shall be comprised of the designated members as set forth below in Section 4.3. The Oversight Committee may designate one or more members of the Oversight Committee as alternate members of any subcommittee, who may replace any absent or disqualified member at any meeting of the subcommittee. If a member of a subcommittee is absent from any meeting, or disqualified from voting thereat, then the remaining member or members present at the meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may, by a unanimous vote, appoint another member of the Oversight Committee to act at the meeting in the place of any such absent or disqualified member. Unless the Oversight Committee provides otherwise, at all meetings of a subcommittee, a majority of the then authorized members of the subcommittee will constitute a quorum, and the vote of a majority of the members of the subcommittee present at any meeting at which there is a quorum will be the act of the subcommittee. Unless the Oversight Committee provides otherwise, each subcommittee designated by the Oversight Committee shall adopt a subcommittee charter and may make, alter, and repeal rules and procedures for the conduct of its business. The Subcommittee charter shall be approved by a vote of a simple majority as set forth in Section 3.13. In the absence of a subcommittee charter, each subcommittee shall conduct its business in the same manner as the Oversight Committee conducts its business. Each subcommittee will have a chairperson, who will be selected by the Oversight Committee at large.

Section 4.2 <u>Certain Subcommittees</u>. Without limiting in any way the previous Section, the following are subcommittees of the Oversight Committee (each of which has the powers and authority set forth in this Article in addition to any other powers and authority as may be delegated to it by the Oversight Committee):

- (a) Executive Subcommittee;
- (b) Audit Subcommittee;
- (c) Board Governance and Ethics Subcommittee;
- (d) Nominations Subcommittee;
- (e) Product Development Subcommittee;
- (f) Scientific Research Subcommittee:
- (g) Prevention Subcommittee; and
- (h) Diversity Subcommittee.

Section 4.3 <u>Executive Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Executive Subcommittee (the "<u>Executive Subcommittee</u>").

- (a) The purpose of the Executive Subcommittee is to transact all normal business referred to it by the Oversight Committee and to conduct the Chief Executive Officer's annual performance review.
- (b) The Executive Subcommittee will be composed of no more than four (4) members of the Oversight Committee. Members of the Executive Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal from their positions by action of the Oversight Committee.
- (c) The Executive Subcommittee shall meet as often as the Chair deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
- (d) Meetings of the Executive Subcommittee shall be conducted in accordance with the Texas Open Meetings Act.

- Section 4.4 <u>Audit Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Audit Subcommittee (the "Audit Subcommittee").
- (a) The purpose of the Audit Subcommittee is to review and make recommendations to the Oversight Committee with respect to the following:
 - (i) The annual operating budget and strategic plan;
 - (ii) Policies for monitoring grant performance;
- (iii) Variances in the operating budget of the Institute of more than 5% or \$25,000;
 - (iv) Non-grant contracts exceeding \$100,000; and
 - (v) Any variance of more than 10% in any announced grant award.
- (b) The members of the Audit Subcommittee will be appointed by the Oversight Committee. The Audit Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Audit Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Audit Subcommittee.
- (c) The Audit Subcommittee shall meet as often as the Chairperson of the Audit Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
 - Section 4.5 <u>Board Governance and Ethics Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Board Governance and Ethics Subcommittee (the "Board Governance and Ethics Subcommittee").
- (a) The purpose of the Board Governance and Ethics Subcommittee is to review and recommend proposed changes for approval to the Oversight Committee with respect to the following:
 - (i) These Bylaws;
 - (ii) Any policies or administrative rules of the Institute;
 - (iii) Legislation regarding or affecting the Institute;
 - (iv) The delegation of authority to the Chief Executive Officer;
 - (v) The ethics policies of the Institute and their administration; and
 - (vi) An annual review of the internal policies and processes of the Oversight Committee.
- (b) The members of the Board Governance and Ethics Subcommittee will be appointed by the Oversight Committee. The Board Governance and Ethics Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Board

Governance and Ethics Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Board Governance and Ethics Subcommittee.

- (c) The Board Governance and Ethics Subcommittee shall meet as often as the Chairperson of the Board Governance and Ethics Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
 - Section 4.6 <u>Nominations Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Nominations Subcommittee (the "<u>Nominations</u> Subcommittee").
- (a) The purpose of the Nominations Subcommittee is to identify members for the Institute's advisory committees and to accept nominations for and recommend candidates to serve as Oversight Committee officers.
- (b) The members of the Nominations Subcommittee will be appointed by the Oversight Committee. The Nominations Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Nominations Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Nominations Subcommittee.
- (c) The Nominations Subcommittee shall meet as often as the Chairperson of the Nominations Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
 - Section 4.7 <u>Product Development Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Product Development Subcommittee (the "<u>Product Development Subcommittee</u>").
- (a) The purpose of the Product Development Subcommittee is to develop policies for the Oversight Committee's adoption that will ensure that the Institute properly exercises its duty to award grants for research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer. In addition, the Product Development Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT product development research grants.
- (b) The members of the Product Development Subcommittee will be appointed by the Oversight Committee. The Product Development Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Product Development Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Product Development Subcommittee.
- (c) The Product Development Subcommittee shall meet as often as the Chairperson of the Product Development Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

- Section 4.8 <u>Scientific Research Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Scientific Research Subcommittee (the "Scientific Research Subcommittee").
- (a) The purpose of the Scientific Research Subcommittee is to provide appropriate program oversight and feedback to the Oversight Committee related to program policies, including, but not limited to, policies for implementing, monitoring, and revising the Texas Cancer Plan. In addition, the Scientific Research Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT scientific research grants. The purpose of the Scientific Research Subcommittee is to develop policies for the Oversight Committee's adoption that will ensure that the Institute properly exercises its duty to award grants for research into the causes of and cures for all types of cancer in humans and to create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer. In addition, the Scientific Research Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT research grants.
- (b) The members of the Scientific Research Subcommittee will be appointed by the Oversight Committee. The Scientific Research Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Scientific Research Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Scientific Research Subcommittee.
- (c) The Scientific Research Subcommittee shall meet as often as the Chairperson of the Scientific Research Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
 - Section 4.9 <u>Prevention Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Prevention Subcommittee (the "<u>Prevention</u> Subcommittee").
- (a) The purpose of the Prevention Subcommittee is to provide appropriate program oversight and feedback to the Oversight Committee related to program policies, including, but not limited to, policies for implementing, monitoring, and revising the Texas Cancer Plan. In addition, the Prevention Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT prevention grants. The purpose of the Prevention Subcommittee is to develop policies for the Oversight Committee's adoption that will ensure that the Institute properly exercises its duty to award grants for cancer prevention and control programs to mitigate the incidence of all types of cancers in humans and to implement the Texas Cancer Plan. In addition, the Prevention Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT prevention grants.
- (b) The members of the Prevention Subcommittee will be appointed by the Oversight Committee. The Prevention Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Prevention Subcommittee will serve until

their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Prevention Subcommittee.

- (c) The Prevention Subcommittee shall meet as often as the Chairperson of the Prevention Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
 - Section 4.10 <u>Diversity Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Diversity Subcommittee (the "<u>Diversity Subcommittee</u>").
- (a) The purpose of the Diversity Subcommittee is to ensure that the Institute makes every effort to outreach to all communities about the cancer research and prevention funding opportunities in the State of Texas.
- (b) The members of the Diversity Subcommittee will be appointed by the Oversight Committee. The Diversity Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Diversity Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Diversity Subcommittee.
- (c) The Diversity Subcommittee shall meet as often as the Chairperson of the Diversity Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

ARTICLE 5 CHAIRPERSON AND VICE CHAIRPERSON

- Section 5.1 <u>Election</u>. The Oversight Committee shall elect from among its members a Chairperson and a Vice Chairperson in accordance with the selection provisions of these Bylaws. Nothing herein restricts the ability of the Oversight Committee to elect additional officers from among its members by a vote of a simple majority of the members of the Oversight Committee.
- Section 5.2 <u>Election</u>, Term of Office and Removal. At the first regular Oversight Committee meeting following the adoption of these bylaws, the members of the Oversight Committee shall elect the Chairperson and Vice Chairperson by a vote of a simple majority as set forth in Section 3.13. Thereafter, the members of the Oversight Committee shall elect the Chairperson and Vice Chairperson by a vote of a simple majority of as set forth in Section 3.13 at the last regular Oversight Committee meeting of the state fiscal year in each odd-numbered year. The Nominations Subcommittee may recommend candidates for the Oversight Committee's consideration prior to the vote by the Oversight Committee. The Chairperson and the Vice Chairperson will hold office until death, resignation, or removal from office, or the election and qualification of a successor, whichever occurs first; provided, however, that neither the Chairperson nor the Vice Chairperson may hold office for two consecutive terms. If the person holding the office or Chairperson or Vice Chairperson holds office for one term, and a successor has not been elected by the Oversight Committee to take office at the expiration of the term, then the person holding the office of Chairperson or Vice Chairperson, as applicable, shall continue to hold the office until such time that a quorum of the Oversight Committee can

meet and elect a successor. The Chairperson or the Vice Chairperson may be removed at any time, with or without cause, by the vote of a simple majority of the members of the Oversight Committee as set forth in Section 3.13. If the office of the Chairperson or the Vice Chairperson becomes vacant for any reason, including by the expiration of the term, then the vacancy must be filled by the vote of a simple majority of the members of the Oversight Committee as set forth in Section 3.13.

- Section 5.3 <u>Chairperson</u>. The Chairperson is the presiding officer of the Oversight Committee. The Chairperson shall preside at each meeting of the Oversight Committee. The Chairperson will also have such authority, duties, roles, and responsibilities as may be assigned by applicable law or recommended by the Board Governance and Ethics Subcommittee and approved by the Oversight Committee. The Chairperson may authorize official duties of members of the Oversight Committee, the University Advisory Committee, or any Ad Hoc Advisory Committee in accordance with applicable law. The Chairperson may not serve as the presiding officer for any other foundation or organization created to specifically benefit the Institute.
- Section 5.4 <u>Vice Chairperson</u>. The Vice Chairperson shall, in the absence of the Chairperson, preside at each meeting of the Oversight Committee. The Vice Chairperson will also have such authority, duties, roles, and responsibilities as may be assigned by the Board Governance and Ethics Subcommittee or applicable law and approved by the Oversight Committee.
- Section 5.5 <u>Presiding Officers in the Absence of the Chairperson and Vice Chairperson.</u> In the absence of the Chairperson and Vice Chairperson, the Chairperson of the Scientific Research Subcommittee shall preside at each meeting of the Oversight Committee. In the absence of Scientific Research Subcommittee Chairperson, then the Chairperson of the Product Development Subcommittee shall preside. In the absence of the Chairpersons of the Scientific Research and Product Development Subcommittees, then the Chairperson of the Prevention Subcommittee shall preside.

ARTICLE 6 THE CHIEF EXECUTIVE OFFICER

- Section 6.1 <u>General Powers</u>. There will be one Chief Executive Officer of the Institute (the "<u>Chief Executive Officer</u>"). The Chief Executive Officer has such powers as are delegated to the Chief Executive Officer by the Oversight Committee and such powers as are vested in the Chief Executive Officer pursuant to applicable law.
- Section 6.2 <u>Selection by the Oversight Committee</u>. The Oversight Committee shall hire the Chief Executive Officer.
- Section 6.3 <u>Performance of Duties</u>. The Chief Executive Officer shall perform the duties of the Chief Executive Officer as provided by these Bylaws, applicable law, or the Oversight Committee. In performance of such duties, the Chief Executive Officer is authorized to execute contracts on behalf of CPRIT. Such authority is limited when CPRIT's enabling statute specifically authorizes the Oversight Committee to enter into a written contract. In that event, the Chief Executive Officer may execute contract(s)

pursuant to a specific delegation by the Oversight Committee. Subject to prior authorization by the Chief Executive Officer, CPRIT's Chief Operating Officer may execute contracts on behalf of CPRIT. The Chief Executive Officer must notify the Oversight Committee in writing prior to authorizing the Chief Operating Officer to execute contracts on behalf of CPRIT; such notification shall specify the time period the Chief Operating Officer is authorized to do so. The Oversight Committee Chairperson and Vice Chairperson may authorize the Chief Operating Officer to execute contracts on behalf of CPRIT and waive prior notification by the Chief Executive Officer upon a finding that an emergency exists preventing such prior notification. The emergency authorization shall be in writing.

- Section 6.4 <u>Grant Review</u>. The Chief Executive Officer shall oversee the grant review process and may terminate grants that do not meet contractual obligations.
- Section 6.5 <u>Quarterly Report</u>. Each quarter, the Chief Executive Officer shall report to the Oversight Committee on any new grant awards and the progress and continued merit of scientific research and prevention programs previously awarded funding. The report must include a summary of the allocation of funding among scientific research and prevention programs and details regarding the final results of completed projects under these programs.
- Section 6.6 <u>Duties Regarding Foundations or Organizations Created to Specifically Benefit CPRIT</u>. The Chief Executive Officer shall annually report to the Oversight Committee on guidelines for the governance of any foundation or organization created specifically to benefit CPRIT and the relationship between the Institute and the foundation or organization. The Chief Executive Officer shall also annually solicit a report from the foundation or organization created specifically to benefit the Institute regarding the funds the foundation or organization holds, the pledges it has received, and the identities of contributors.

ARTICLE 7 OTHER OFFICERS OF THE INSTITUTE

- Section 7.1 <u>Creation and Selection of Other Officers of the Institute</u>. The Oversight Committee may direct the Chief Executive Officer to create other officer positions of the Institute and to hire individuals to fill such positions.
- Section 7.2 <u>Certain Officers</u>. Without limiting in any way the previous Section, the following officer positions of the Institute have been created (each of which has the duties and authority set forth in this Article in addition to any other duties and authority as may be delegated to such officer by the Oversight Committee):
- (a) Chief Operating Officer, whose duties include oversight of the Institute's daily operations, including financial administration, grants management administration, communications, governmental relations, and information technology services;
- (b) Chief Compliance Officer, whose duties include reporting to the Oversight Committee on the agency's compliance with applicable law, administrative rules, and policies, and building, developing, and maintaining a compliance program that fosters ethical business

behavior and includes requirements for risk assessments, program governance, metrics, and reporting;

- (c) Chief Scientific Officer, whose duties include oversight of the scientific research application submission process, coordinating the review of research proposals, monitoring grant progress, and fostering collaboration among the cancer and disease scientific research community to maximize the Institute's impact
- (d) Chief Product Development Officer, whose duties include oversight of the cancer research development application submission process, coordinating review of the cancer research product development proposals, monitoring grant progress and fostering collaboration among the bioscience community to maximize the Institute's impact;
- (e) Chief Prevention Officer, whose duties include oversight of the prevention application submission process, coordinating the review of prevention proposals, monitoring grant progress, and fostering collaboration among the cancer and disease prevention community to maximize the Institute's impact; and
- (f) General Counsel, whose duties include oversight of the legal issues that arise as part of the Institute's operations.

ARTICLE 8 COMMITTEES OF THE INSTITUTE

- Section 8.1 <u>Creation of Committees of the Institute</u>. Pursuant to applicable law and in accordance with this Article, the Oversight Committee may create Committees of the Institute and appoint and approve members of such committees.
- Section 8.2 <u>Scientific Research and Prevention Program Committee</u>. There will be one or more scientific research and prevention programs committees of the Institute (each, a "<u>Scientific Research and Prevention Programs Committee</u>"). Each Scientific Research and Prevention Programs Committee has such powers as are vested in it pursuant to applicable law. The Chief Executive Officer, with approval by simple majority of the members of the Oversight Committee as set forth in Section 3.13, shall appoint as members of one or more Scientific Research and Prevention Programs Committees experts in the field of cancer research, prevention, and patient advocacy to serve for terms as determined by the Chief Executive Officer. Individuals appointed to a Scientific Research and Prevention Programs Committee may be residents of another state. A member of a Scientific Research and Prevention Programs Committee may receive an honorarium according to a policy developed by the Chief Executive Officer in consultation with the Oversight Committee.
- Section 8.3 <u>University Advisory Committee</u>. There will be one university advisory committee of the Institute (the "<u>University Advisory Committee</u>"). The University Advisory Committee has such powers as are vested in it pursuant to applicable law. The University Advisory Committee shall advise the Oversight Committee and each Scientific Research and Prevention Programs Committee regarding the role of institutions of higher education in cancer research. The University Advisory Committee is composed

of the following members to serve for the term as determined by the appropriate appointing authority appointing such member:

- (a) two members appointed by the chancellor of The University of Texas System to represent:
 - (i) The University of Texas Southwestern Medical Center at Dallas;
 - (ii) The University of Texas Medical Branch at Galveston;
 - (iii) The University of Texas Health Science Center at Houston;
 - (iv) The University of Texas Health Science Center at San Antonio;
 - (v) The University of Texas Health Center at Tyler; or
 - (vi) The University of Texas M. D. Anderson Cancer Center;
- (b) one member appointed by the chancellor of The Texas A&M University System to represent:
 - (i) The Texas A&M University System Health Science Center; or
- (ii) the teaching hospital for The Texas A&M Health Science Center College of Medicine;
- (c) one member appointed by the chancellor of the Texas Tech University System to represent the Texas Tech University Health Sciences Center;
- (d) one member appointed by the chancellor of the University of Houston System to represent the system;
- (e) one member appointed by the chancellor of the Texas State University System to represent the system;
- (f) one member appointed by the chancellor of the University of North Texas System to represent the system;
 - (g) one member appointed by the president of Baylor College of Medicine;
 - (h) one member appointed by the president of Rice University; and
- (i) members appointed at the Chief Executive Officer's discretion by the chancellors of other institutions.
 - Section 8.4 <u>Ad Hoc Advisory Committee on Childhood Cancers</u>. The Oversight Committee shall create an ad hoc committee of experts to address childhood cancers. Members of the Ad Hoc Advisory Committee on Childhood Cancers shall be appointed by the Oversight Committee and serve for terms determined by the Oversight Committee. The Ad Hoc Advisory Committee on Childhood Cancers has the duties and authority set

forth in the advisory committee's charter in addition to any other duties and authority as may be delegated by the Oversight Committee.

Section 8.5 Other Ad Hoc Advisory Committees of the Institute. The Oversight Committee, as necessary, may create additional ad hoc committees of experts to advise the Oversight Committee on issues relating to cancer. The number of members of each Ad Hoc Committee will be determined by the Oversight Committee. Ad Hoc Advisory Committee members are appointed by the Oversight Committee and serve for terms determined by the Oversight Committee.

Section 8.6 <u>Certain Ad Hoc Advisory Committees of the Institute</u>. Without limiting in any way the previous Section, the following are the Ad Hoc Advisory Committees of the Institute (each of which has the powers and authority set forth in this Article in addition to any other powers and authority as may be delegated to it by the Oversight Committee):

- (a) Scientific and Prevention Advisory Council; and
- (b) Product Development Advisory Committee;

Section 8.7 <u>Annual Report to the Oversight Committee</u>. Each Committee of the Institute shall report to the Oversight Committee at least annually regarding the work undertaken by such committee pursuant to a schedule and format dictated by the Oversight Committee.

ARTICLE 9 CODE OF CONDUCT AND ETHICS POLICY

Section 9.1 <u>Adopted by Reference</u>. The Oversight Committee herein by reference incorporates the *Code of Conduct and Ethics Policy* as approved by the Oversight Committee on February 25, 2013 and all approved amendments.

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STATEMENT OF REVISIONS

Approved November 1, 2013

Changes made to Sections 2.2, 3.2, 3.3(a) and (b), 3.4, 3.7, 3.15, 4.1, 4.2, 4.3(a) and(b), 4.4(a)(iii), 4.5(a)(iv), 4.6, 4.7, 4.8(a) and(b), 4.9(a) and(b), 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 7.1, 7.2(b) and (d), 8.2, 8.3(i), 8.4, 9.1, Article 6 (title), and Article 9 (title) and text.

Reason for change(s): Revisions made to reflect statutory changes adopted in 2013 legislative session.

Approved May 21, 2014

Changes made to Sections 4.4(a)(ii), 8.6(b)

Reason for change(s): Revision made to reflect statutory changes adopted in 2013 legislative session and to change name of certain ad hoc advisory committees.

Approved May 20, 2015

Changes made to Section 4.6(a) and Section 5.2

Reason for change(s): Revision made to assign Nominations Subcommittee the responsibilities associated with officer elections.

Approved September 10, 2015

Nonsubstantive changes made to Article 9 to correct typographical errors.

Approved November 19, 2015

Change made to Section 6.3.

Reason for change: Clarifies the Chief Executive Officer's contract execution authority and process for delegating such authority to the Chief Operating Officer.

Proposed Assignments By Subcommittee

Proposed Chairs are in bold, new subcommittee members are underlined

OPERATIONS SUBCOMMITTEES				PROGRAM SUBCOMMITTEES			
Audit	Governance	Diversity	Nominations	Contract Terms	Prevention	Acad. Research	Product Dev
<u>Margo</u>	Holmes	Mulrow	Holmes	Montgomery	Mulrow	Rice	Rosenfeld
Rice	Rice	Rosenfeld	Angelou	<u>Holmes</u>	<u>Holmes</u>	Mitchell	Angelou
Angelou	Geren	Mitchell	Mitchell	Rosenfeld	Geren	Montgomery	<u>Margo</u>
Montgomery	<u>Margo</u>			Geren		Mulrow	Rice

Proposed Subcommittee Assignments By Member

Proposed Chairs are in bold, new subcommittee members are underlined

Angelou (3) Audit, <u>Nominations</u>, Product Development

Geren (3) Governance, Prevention, Contract Terms

Holmes (4) Governance, Nominations, Contract Terms, Prevention

Margo (3) Audit, Governance, Product Development

Mitchell (3) Diversity, <u>Nominations</u>, <u>Academic Research</u>

Montgomery (3) Audit, Contract Terms, Academic Research

Mulrow (3) **Diversity, Prevention**, Academic Research

Rice (4) Audit, Governance, **Academic Research**, Product Development

Rosenfeld (3) <u>Diversity</u>, Contract Terms, **Product Development**



MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS

From: NED HOLMES, CHAIR BOARD GOVERNANCE SUBCOMMITTEE

Subject: INTENTION TO RECOMMEND APPROVAL AND PUBLICATION

OF PROPOSED CHANGES TO ADMINISTRATIVE RULES

NOVEMBER 4, 2015

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee approve the proposed amendments to 25 T.A.C. Chapter 703 for publication in the *Texas Register*. The Board Governance Subcommittee reviewed and discussed the proposed amendments with CPRIT's General Counsel at its meeting on November 4, 2015.

Discussion

CPRIT staff conducts an annual review of existing procedures related to grant applications, grant award contracting, and grant monitoring. Based upon this review, CPRIT staff identified certain rule provisions to be changed in order to provide additional clarity for grant applicants and grantees and to align administrative rules with current processes. Once approved by the Oversight Committee, the proposed rule changes will be published in the *Texas Register* and be available through CPRIT's website. The public may provide input on the proposed changes. Written comments may be submitted for at least 30 days from the time that the changes are available in the *Texas Register*.

The Board Governance Subcommittee has reviewed the proposed amendments and recommends that the Oversight Committee approve publication. After the public comment period ends, any comments on the proposed rules will be summarized and considered by the Oversight Committee before the rules are finally adopted at the February meeting.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas (Institute) proposes amendments to §§ 703.3, 703.11, 703.12, 703.13, 703.14, 703.20, and 703.21 regarding Requests for Applications, clarification on grant applications, matching form due dates, the prevention percentage of overall grant funds, grantee audit requirements, no cost extensions, tobacco free policy waivers, and report due dates along with report approval rules. The proposed changes affect the application process as well as grantee requirements.

Background and Justification

§ 703.3 is first amended to remove the requirement that a Request for Applications (RFAs) be published in the Texas Register. RFAs will still be published on CPRIT's website and announced via an electronic list serve messaging service. This amendment removes a duplicative step in the RFA process that is less effective than other methods used to publish RFAs.

The second change to § 703.3 adds a new subsection to clarify that CPRIT staff or CPRIT's third party grants administrator may contact the grant applicant to seek clarification on information provided in the grant application or to request additional information to facilitate the administrative review process. This change addresses occasional issues that arise when information on a document submitted by a grant applicant is unclear or the document appears to be missing a page. Requests for clarification or additional information must be approved by the Program Officer before the grant applicant is contacted. A record of requests will be made for review by the Chief Compliance Officer.

§ 703.11 is amended to change the due date of matching verification forms. Currently, these forms are due 60 days after the anniversary date of the effective date of the grant contract. Matching verification forms are based on grantee expenditures as reported in each Financial Status Report (FSRs) and cannot be completed until the last FSR of the last quarter of the fiscal year is submitted. FSRs are due 90 days after the end of the fiscal quarter, which occurs after the current due date of the matching verification form. This amendment changes the matching verification form due date so that it falls after the submission of the last quarter FSR.

§ 703.12 is amended to clarify that the annual ten percent cap on the allocation of grant award funds to cancer prevention grants is calculated based upon the "full amount of grant award funds available to be awarded for the fiscal year" announced by CPRIT's CEO at the first regular Oversight Committee meeting of the fiscal year (and updated periodically). The clarification is necessary because unanticipated declinations of research grant awards, particularly recruitment awards, after the last regular meeting of the fiscal year may impact the calculation of the total amount available to the prevention program. Specifying the expected amount of the total award funds available provides budgetary certainty for the prevention program and increases the transparency of CPRIT's processes.

§ 703.13 is amended to remove "program specific independent audit" from the accepted ways a grantee can fulfill the audit requirement. Grantees who expend \$500,000 or more in state awards during its fiscal year are required to submit an audit. Currently an audit must be completed in one of the following formats: a single independent audit, a program specific audit, or an agreed upon procedures engagement. CPRIT's internal auditor recommended that CPRIT remove "program specific independent audit" from its administrative rules because it is duplicative of the agreed upon procedures, which was developed by CPRIT's internal auditor.

§ 703.14 is amended to implement a process for reviewing and approving no cost extensions that are requested after the specified due date. By rule, no cost extensions are due no sooner than 180 days and no later than 30 days before the end date of the grant contract. The amendment allows the Chief Executive Officer (CEO) to review and approve a request submitted outside the specified time and approve it for good cause. If approved, the CEO must provide a written justification to the Oversight Committee.

§ 703.20 is amended to specify what a grantee must do in order to request a waiver to the tobacco free policy for research purposes. If a research project is conducted at the entity that requires tobacco, the grantee must specify the research project conducted with the use of tobacco as well as the location for the waiver to be considered for approval.

§ 703.21 is amended to allow a grantee more time in filing required grantee reports if the execution date of a grant contract occurs after the effective date. Due date of grantee reports are based off of the effective date of a grant contract; however, in some cases a contract is not executed until after the effective date thus giving a grantee less time to submit reports. The rule change permits the Program Officer to approve time to submit reports that are late because of a delay in starting the project after the effective date. This rule is also amended to require the following reports be approved by CPRIT (as opposed to submitted) in order for a grantee to receive disbursement of grant funds: matching funds, progress reports (including annual, quarterly, and final), and FSRs. This change was recommended by CPRIT's internal auditors.

Fiscal Note

Kristen Pauling Doyle, General Counsel for the Cancer Prevention and Research Institute of Texas, has determined that for the first five-year period the rule changes are in effect there will be no foreseeable implications relating to costs or revenues for state or local government as a result of enforcing or administering the rules.

Public Benefit and Costs

Ms. Doyle has determined that for each year of the first five years the rule changes are in effect the public benefit anticipated as a result of enforcing the rules will be clarification of policies and procedures the Institute will follow to implement its statutory duties.

Small Business and Micro-business Impact Analysis

Ms. Doyle has determined that the rule changes shall not have an effect on small businesses or

on micro businesses.

Written comments on the proposed rule changes may be submitted to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711 no later than January 4, 2016. Parties filing comments are asked to indicate whether or not they support the rule revisions proposed by the Institute and, if a change is requested, to provide specific text proposed to be included in the rule. Comments may be submitted electronically to kdoyle@cprit.state.tx.us. Comments may be submitted by facsimile transmission to 512/475-2563.

Statutory Authority

The rule changes are proposed under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter. Kristen Pauling Doyle, the Institute's General Counsel, has reviewed the proposed amendment and certifies the proposal to be within the Institute's authority to adopt.

There is no other statute, article or code that is affected by these rules.



Summary of Proposed Rule Changes November 2015

Rule § 703.3 Grant Applications

The first change removes the requirement that a Request for Applications (RFAs) be published in the Texas Register. RFAs will still be published on CPRIT's website and announced via an electronic list serve messaging service. This amendment removes a duplicative step in the RFA process that is less effective than other methods used to publish RFAs.

The second change to § 703.3 adds a new subsection to clarify that CPRIT staff or CPRIT's third party grants administrator may contact the grant applicant to seek clarification on information provided in the grant application or to request additional information to facilitate the administrative review process. This change addresses occasional issues that arise when information on a document submitted by a grant applicant is unclear or the document appears to be missing a page. Requests for clarification or additional information must be approved by the Program Officer before the grant applicant is contacted. A record of requests will be made for review by the Chief Compliance Officer.

Rule § 703.11 Requirement to Demonstrate Available Funds for Cancer Research Grants

The proposed amendment to the matching requirement changes the due date of matching verification forms. Currently, these forms are due 60 days after the anniversary date of the effective date of the grant contract. Matching verification forms are based on grantee expenditures as reported in each Financial Status Report (FSRs) and cannot be completed until the last FSR of the last quarter of the fiscal year is submitted. FSRs are due 90 days after the end of the fiscal quarter, which occurs after the current due date of the matching verification form. This amendment changes the matching verification form due date so that it falls after the submission of the last quarter FSR.

Rule § 703.13 Audits and Investigations

The proposed amendment would remove "program specific independent audit" from the accepted ways a grantee can fulfill the audit requirement. Grantees who expend \$500,000 or more in state awards during its fiscal year are required to submit an audit. Currently an audit must be completed in one of the following formats: a single independent audit, a program specific audit, or an agreed upon procedures engagement. CPRIT's internal auditor recommended that CPRIT remove "program specific independent audit" from its administrative rules because it is duplicative of the agreed upon procedures, which was developed by CPRIT's internal auditor.

Rule § 703.12 Limitation on Use of Funds

The proposed amendment clarifies that the annual ten percent cap on the allocation of grant award funds to cancer prevention grants is calculated based upon the "full amount of grant award funds available to be awarded for the fiscal year" announced by CPRIT's CEO at the first regular Oversight Committee meeting of the fiscal year (and updated periodically). The clarification is necessary because unanticipated declinations of research grant awards, particularly recruitment awards, after the last regular meeting of the fiscal year may impact the calculation of the total amount available to the prevention program. Specifying the expected amount of the total award funds available provides budgetary certainty for the prevention program and increases the transparency of CPRIT's processes.

Rule § 703.14 Termination, Extension, and Close Out of Grant Contracts

The proposed amendment implements a process for reviewing and approving no cost extensions that are requested after the specified due date. By rule, no cost extensions are due no sooner than 180 days and no later than 30 days before the end date of the grant contract. The amendment allows the Chief Executive Officer (CEO) to review and approve a request submitted outside the specified time and approve it for good cause. If approved, the CEO must provide a written justification to the Oversight Committee.

Rule § 703.20 Certification of Tobacco-Free Policy for Grant Recipients

The proposed amendment specifies what a grantee must do in order to request a waiver to the tobacco free policy for research purposes. If a research project is conducted at the entity that requires tobacco, the grantee must specify the research project conducted with the use of tobacco as well as the location where the project is conducted.

Rule § 703.21 Monitoring Grant Award Performance and Expenditures

One of the proposed amendments would allow a grantee more time in filing required grantee reports if the execution date of a grant contract occurs after the effective date. Due date of grantee reports are based off of the effective date of a grant contract; however, in some cases a contract is not executed until after the effective date, thus giving a grantee less time to submit reports. The rule change permits the Program Officer to approve time to submit reports that are late because of a delay in starting the project after the effective date. This rule is also amended to require the following reports be approved by CPRIT (as opposed to submitted) in order for a grantee to receive disbursement of grant funds: matching funds, progress reports (including annual, quarterly, and final), and FSRs. This change was recommended by CPRIT's internal auditors.

Rule § 703.3 Grant Applications

- (a) The Institute shall accept Grant Applications for Cancer Research and Cancer Prevention programs to be funded by the Cancer Prevention and Research Fund or the proceeds of general obligation bonds issued on behalf of the Institute in response to standard format Requests for Applications issued by the Institute.
- (b) Each Request for Applications shall be publicly announced in the Texas Register and available through the Institute's Internet website. The Institute reserves the right to modify the format and content requirements for the Requests for Applications from time to time. Notice of modifications will be announced and available through the Institute's Internet website. The Request for Applications shall:
- (1) Include guidelines for the proposed projects and may be accompanied by instructions provided by the Institute.
- (2) State the criteria to be used during the Grant Review Process to evaluate the merit of the Grant Application, including guidance regarding the range of possible scores.
- (A) The specific criteria and scoring guidance shall be developed by the Chief Program Officer in consultation with the Review Council.
- (B) When the Institute will use a preliminary evaluation process as described in §703.6 of this chapter (relating to Grants Review Process) for the Grant Applications submitted pursuant to a particular Grant Mechanism, the Request for Applications shall state the criteria and Grant Application components to be included in the preliminary evaluation.
- (c) Requests for Applications for Cancer Research and Cancer Prevention projects issued by the Institute may address, but are not limited to, the following areas:
- (1) Basic research;
- (2) Translational research, including proof of concept, preclinical, and Product Development activities;
- (3) Clinical research;
- (4) Population based research;
- (5) Training;
- (6) Recruitment to the state of researchers and clinicians with innovative Cancer Research approaches;
- (7) Infrastructure, including centers, core facilities, and shared instrumentation;
- (8) Implementation of the Texas Cancer Plan; and
- (9) Evidence based Cancer Prevention education, outreach, and training, and clinical programs and services.

- (d) An otherwise qualified applicant is eligible solely for the Grant Mechanism specified by the Request for Applications under which the Grant Application was submitted.
- (e) The request for Grant Applications for Cancer Research projects shall seek information from Grant Applicants regarding whether the proposed project has Product Development prospects, including, but not limited to anticipated regulatory filings, commercial abstracts or business plans.
- (f) Failure to comply with the material and substantive requirements set forth in the Request for Applications may serve as grounds for disqualification from further consideration of the Grant Application by the Institute. A Grant Application determined by the Institute to be incomplete or otherwise noncompliant with the terms or instructions set forth by the Request for Applications shall not be eligible for consideration of a Grant Award.
- (g) Only those Grant Applications submitted via the designated electronic portal designated by the Institute by the deadline, if any, stated in the Request for Applications shall be eligible for consideration of a Grant Award.
- (1) Nothing herein shall prohibit the Institute from extending the submission deadline for one or more Grant Applications upon a showing of good cause.
- (2) The Institute shall document any deadline extension granted, including the reason for extending the deadline and will cause the documentation to be maintained as part of the Grant Review Process records.
- (h) The Grant Applicant shall certify that it has not made and will not make a donation to the Institute or any foundation created to benefit the Institute.
- (1) Grant Applicants that make a donation to the Institute or any foundation created to benefit the Institute on or after June 14, 2013, are ineligible to be considered for a Grant Award.
- (2) For purposes of the required certification, the Grant Applicant includes the following individuals or the spouse or dependent child(ren) of the following individuals:
 - (A) the Principal Investigator, Program Director, or Company Representative;
 - (B) a Senior Member or Key Personnel listed on the Grant Application;
 - (C) an officer or director of the Grant Applicant.
- (3) Notwithstanding the foregoing, one or more donations exceeding \$500 by an employee of a Grant Applicant not described by paragraph (2) of this subsection shall be considered to be made on behalf of the Grant Applicant for purposes of the certification.
- (4) The certification shall be made at the time the Grant Application is submitted.
- (5) The Chief Compliance Officer shall compare the list of Grant Applicants to a current list of donors to the Institute and any foundation created to benefit the Institute.
- (6) To the extent that the Chief Compliance Officer has reason to believe that a Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, the Chief Compliance Officer shall seek information from the Grant Applicant to resolve any issue. The Grant

Application may continue in the Grant Review Process during the time the additional information is sought and under review by the Institute.

- (7) If the Chief Compliance Officer determines that the Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, then the Institute shall take appropriate action. Appropriate action may entail:
 - (A) Withdrawal of the Grant Application from further consideration;
- (B) Return of the donation, if the return of the donation is possible without impairing Institute operations.
- (8) If the donation is returned to the Applicant, then the Grant Application is eligible to be considered for a Grant Award.
- (i) Grant Applicants shall identify by name all sources of funding, including a capitalization table that reflects private investors, if any, contributing to the project proposed for a Grant Award. This information shall include those individuals or entities that have an investment, stock or rights in the project. The Institute shall make the information provided by the Grant Applicant available to Scientific Research and Prevention Programs Committee members, Institute employees, independent contractors participating in the Grant Review Process, Program Integration Committee Members and Oversight Committee Members for purposes of identifying potential Conflicts of Interest prior to reviewing or taking action on the Grant Application. The information shall be maintained in the Institute's Grant Review Process records.
- (j) A Grant Applicant shall indicate if the Grant Applicant is currently ineligible to receive Federal or State grant funds due to debarment or suspension or if the Grant Applicant has had a grant terminated for cause within five years prior to the submission date of the Grant Application. For purposes of the provision, the term Grant Applicant includes the Senior Member and Key Personnel.
- (k) The Institute may require each Grant Applicant for a Cancer Research Grant Award for Product Development to submit an application fee.
- (1) The Chief Executive Officer shall adopt a policy regarding the application fee amount.
- (2) The Institute shall use the application fee amounts to defray the Institute's costs associated with the Product Development review processes, including due diligence and intellectual property reviews, as specified in the Request for Application.
- (I) During the course of administrative review of the Grant Application, the Institute may contact the Grant Applicant to seek clarification on information provided in the Grant Application or to request additional information if such information clarifies the Grant Application. The Institute shall keep a record of requests made under this subsection for review by the Chief Compliance Officer.

Rule § 703.11 Requirement to Demonstrate Available Funds for Cancer Research Grants

- (a) Prior to the disbursement of Grant Award funds, the Grant Recipient of a Cancer Research Grant Award shall demonstrate that the Grant Recipient has an amount of Encumbered Funds equal to one-half of the Grant Award available and not yet expended that are dedicated to the research that is the subject of the Grant Award. The Grant Recipient's written certification of Matching Funds, as described in this section, shall be included in the Grant Contract. A Grant Recipient of a multiyear Grant Award may certify Matching Funds on a year-by-year basis for the amount of Award Funds to be distributed for the Project Year based upon the Approved Budget. A Grant Recipient receiving multiple Grant Awards may provide certification at the institutional level.
- (b) For purposes of the certification required by subsection (a) of this section, a Grant Recipient that is a public or private institution of higher education, as defined by §61.003, Texas Education Code, may credit toward the Grant Recipient's Matching Funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the Grant Recipient and the five percent (5%) Indirect Cost limit imposed by §102.203(c), Texas Health and Safety Code, subject to the following requirements:
- (1) The Grant Recipient shall file certification with the Institute documenting the federal indirect cost rate authorized for research grants awarded to the Grant Recipient;
- (2) To the extent that the Grant Recipient's Matching Funds credit does not equal or exceed one-half of the Grant Award funds to be distributed for the Project Year, then the Grant Recipient's Matching Funds certification shall demonstrate that a combination of the dollar amount equivalent credit and the funds to be dedicated to the Grant Award project as described in subsection (c) of this section is available and sufficient to meet or exceed the Matching Fund requirement;
- (3) Calculation of the portion of federal indirect cost rate credit associated with subcontracted work performed for the Grant Recipient shall be in accordance with the Grant Recipient's established internal policy; and
- (4) If the Grant Recipient's federal indirect cost rate changes less than six months following the anniversary of the Effective Date of the Grant Contract, then the Grant Recipient may use the new federal indirect cost rate for the purpose of calculating the Grant Recipient's Matching Funds credit for the entirety of the Project Year.
- (c) For purposes of the certification required by subsection (a) of this section, Encumbered Funds must be spent directly on the Grant Project or spent on closely related work that supports, extends, or facilitates the Grant Project and may include:
- (1) Federal funds, including, but not limited to American Recovery and Reinvestment Act of 2009 funds, and the fair market value of drug development support provided to the recipient by the National Cancer Institute or other similar programs;
- (2) State of Texas funds;
- (3) funds of other states;

- (4) Non-governmental funds, including private funds, foundation grants, gifts and donations;
- (5) Unrecovered Indirect Costs not to exceed ten percent (10%) of the Grant Award amount, subject to the following conditions:
- (A) These costs are not otherwise charged against the Grant Award as the five percent (5%) indirect funds amount allowed under §703.12(c) of this chapter (relating to Limitation on Use of Funds);
- (B) The Grant Recipient must have a documented federal indirect cost rate or an indirect cost rate certified by an independent accounting firm; and
- (C) The Grant Recipient is not a public or private institution of higher education as defined by §61.003 of the Texas Education Code.
- (6) Funds contributed by a subcontractor or subawardee and spent on the Grant Project, so long as the subcontractor's or subawardee's portion of otherwise allowable Matching Funds for a Project Year may not exceed the percentage of the total Grant Funds paid to the subcontractor or subawardee for the same Project Year.
- (d) For purposes of the certification required by subsection (a) of this section, the following items do not qualify as Encumbered Funds:
- (1) In-kind costs;
- (2) Volunteer services furnished to the Grant Recipient;
- (3) Noncash contributions;
- (4) Income earned by the Grant Recipient that is not available at the time of Grant Award;
- (5) Pre-existing real estate of the Grant Recipient including building, facilities and land;
- (6) Deferred giving such as a charitable remainder annuity trust, a charitable remainder unitrust, or a pooled income fund; or
- (7) Other items as may be determined by the Oversight Committee.
- (e) To the extent that a Grant Recipient of a multiyear Grant Award elects to certify Matching Funds on a yearly basis, the failure to provide certification of Encumbered Funds at the appropriate time for each Project Year shall serve as grounds for terminating the Grant Contract.
- (f) In no event shall Grant Award funds for a Project Year be advanced or reimbursed, as may be appropriate for the Grant Award and specified in the Grant Contract, until the certification required by subsection (a) of this section is filed and approved by the Institute.
- (g) No later than 60 days from the anniversary of the Effective Date of the Grant Contract 30 days following the due date of the FSR reflecting expenses incurred during the last quarter of the Grant Recipient's Project Year, the Grant Recipient shall file a form with the Institute reporting the amount of Matching Funds spent for the preceding Project Year.

- (h) If the Grant Recipient failed to expend Matching Funds equal to one-half of the actual amount of Grant Award funds distributed to the Grant Recipient for the same period, the Institute shall:
- (1) Carry forward and add to the Matching Fund requirement for the next Project Year the dollar amount equal to the deficiency between the actual amount of Grant Award funds distributed and the actual Matching Funds expended, so long as the deficiency is equal to or less than twenty percent (20%) of the total Matching Funds required for the same period and the Grant Recipient has not previously had a Matching Funds deficiency for the project;
- (2) Suspend distributing Grant Award funds for the project to the Grant Recipient if the deficiency between the actual amount of Grant Funds distributed and the Matching Funds expended is greater than twenty percent (20%) but less than fifty percent (50%) of the total Matching Funds required for the period.
- (A) The Grant Recipient will have no less than eight months from the anniversary of the Grant Contract's effective date to demonstrate that it has expended Encumbered Funds sufficient to fulfill the Matching Funds deficiency for the project.
- (B) If the Grant Recipient fails to fulfill the Matching Funds deficiency within the specified period, then the Grant Contract shall be considered in default and the Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract;
- (3) Declare the Grant Contract in default if the deficiency between the actual amount of Grant Award funds distributed and the Matching Funds expended is greater than fifty percent (50%) of the total Matching Funds required for the period. The Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract; or
- (4) Take appropriate action, including withholding reimbursement, requiring repayment of the deficiency, or terminating the Grant Contract if a deficiency exists between the actual amount of Grant Award funds distributed and the Matching Funds expended and it is the last year of the Grant Contract;
- (i) Nothing herein shall preclude the Institute from taking action other than described in subsection (h) of this section based upon the specific reasons for the deficiency. To the extent that other action not described herein is taken by the Institute, such action shall be documented in writing and included in Grant Contract records. The options described in subsection (h)(1) and (2) of this section may be used by the Grant Recipient only one time for the particular project. A second deficiency of any amount shall be considered an event of default and the Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract.
- (j) The Grant Recipient shall maintain adequate documentation supporting the source and use of the Matching Funds reported in the certification required by subsection (a) of this section. The Institute shall conduct an annual review of the documentation supporting the source and use of Matching Funds reported in the required certification for a risk-identified sample of Grant Recipients. Based upon the results of the sample, the Institute may elect to expand the review of supporting documentation to other Grant Recipients. Nothing herein restricts the authority of the Institute to review supporting documentation for one or more Grant Recipients or to conduct a review of Matching Funds documentation more frequently.

RULE §703.12 Limitation on Use of Funds

- (a) A Grant Recipient may use Grant Award funds only for Cancer Research and Cancer Prevention projects consistent with the purpose of the Act, and in accordance with the Grant Contract. Grant Award funds may not be used for purposes other than those purposes for which the grant was awarded. The Institute may require a Grant Recipient to repay Grant Award funds if the Grant Recipient fails to expend the Grant Award funds in accordance with the terms and conditions of the Grant Contract and the provisions of this chapter.
- (b) Grant Award funds must be used for Authorized Expenses.
- (1) Expenses that are not authorized and shall not be paid from Grant Award funds, include, but are not limited to:
 - (A) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.
 - (B) Contributions to a contingency reserve or any similar provision for unforeseen events.
 - (C) Contributions and donations made to any individual or organization.
- (D) Costs of entertainment, amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.
- (E) Costs relating to food and beverage items, unless the food item is related to the issue studied by the project that is the subject of the Grant Award.
- (F) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.
 - (G) An honorary gift or a gratuitous payment.
 - (H) Interest and other financial costs related to borrowing and the cost of financing.
- (I) Legislative expenses such as salaries and other expenses associated with lobbying the state or federal legislature or similar local governmental bodies, whether incurred for purposes of legislation or executive direction.
 - (J) Liability insurance coverage.
- (K) Benefit replacement pay or legislatively-mandated pay increases for eligible general revenuefunded state employees at Grant Recipient state agencies or universities.
 - (L) Professional association fees or dues for the Grant Recipient or an individual.
- (M) Promotional items and costs relating to items such as T-shirts, coffee mugs, buttons, pencils, and candy that advertise or promote the project or Grant Recipient.
- (N) Patient support services costs relating to services such as personal care items and financial assistance for low-income clients.

- (2) Additional guidance regarding Authorized Expenses for a specific program may be provided by the terms of the Grant Contract and by the Uniform Grant Management Standards (UGMS) adopted by the Comptroller's Office. If guidance from UGMS on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, Texas Health and Safety Code, or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.
- (3) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Authorized Expense.
- (c) A Grant Recipient of Grant Award funds for a Cancer Research project may not spend more than five percent (5%) of the Grant Award funds for Indirect Costs.
- (d) The Institute may not award more than five percent (5%) of the total Grant Award funds for each fiscal year to be used for facility purchase, construction, remodel, or renovation purposes during any year. Any Grant Award funds that are to be expended by a Grant Recipient for facility purchase, construction, remodel, or renovations are subject to the following conditions:
- (1) The use of Grant Award funds must be specifically approved by the Chief Executive Officer with notification to the Oversight Committee;
- (2) Grant Award funds spent on facility purchase, construction, remodel, or renovation projects must benefit Cancer Prevention and Research;
- (3) If Grant Award funds are used to build a capital improvement, then the state retains a lien or other interest in the capital improvement in proportion to the percentage of the Grant Award funds used to pay for the capital improvement. If the capital improvement is sold, then the Grant Recipient agrees to repay to the state the Grant Award funds used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale.
- (e) The Institute may not award more than ten percent (10%) of the money awarded from the Cancer Prevention and Research Fund or from the proceeds of bonds issued on behalf of the Institute to be used for Cancer Prevention and Control programs during any year. Grant Awards for Cancer Prevention research projects shall not be counted toward the Grant Award amount limit for Cancer Prevention and Control Programs. For purposes of this subsection, the Institute is presumed to award the full amount of funds available. At the first regular Oversight Committee meeting of the fiscal year, the Chief Executive Officer shall report that full amount of Grant Award funds available to be awarded for the fiscal year subject to periodic updates announced at regular meetings of the Oversight Committee.

Rule § 703.13 Audits and Investigations

- (a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or investigators working on behalf of the Institute, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the end of the Grant Recipient's fiscal year during which the Grant Contract was terminated.
- (b) Notwithstanding the foregoing, a Grant Recipient expending \$500,000 or more in state awards during its fiscal year shall obtain either an annual single independent audit, a program specific independent audit, or an agreed upon procedures engagement as defined by the American Institute of Certified Public Accountants.
- (1) A single audit is required if funds from more than one state program are spent by a Grant Recipient that does not meet the definition of an institution of higher education in Texas Education Code, §61.003.
- (2) The audited time period is the Grant Recipient's fiscal year.
- (3) The audit must be submitted to the Institute within 30 days of receipt by the Grant Recipient but no later than 270 days following the close of the Grant Recipient's fiscal year and shall include a corrective action plan that addresses any weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit report and a summary of the action taken by the Grant Recipient to address the concerns, if any, raised by the audit report.
- (A) The Grant Recipient may seek additional time to submit the required audit and corrective action plan by providing a written explanation for its failure to timely comply and providing an expected time for the submission.
- (B) The Grant Recipient's request for additional time must be submitted on or before the due date of the required audit and corrective action plan. For purposes of this rule, the "due date of the required audit" is no later than the 270th day following the close of the Grant Recipient's fiscal year.
- (C) Approval of the Grant Recipient's request for additional time is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.
- (c) No reimbursements or advances of Grant Award funds shall be made to the Grant Recipient if the Grant Recipient is delinquent in filing the required audit and corrective action plan. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may receive reimbursements or advances of Grant Award funds during the pendency of the delinquency unless the Institute's approval declines to permit reimbursements or advances of Grant Award funds until the delinquency is addressed.
- (d) A Grant Recipient that is delinquent in submitting to the Institute the audit and corrective action plan required by this section is not eligible to be awarded a new Grant Award or a continuation Grant Award until the required audit and corrective action plan are submitted. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may

remain eligible to be awarded a new Grant Award or a continuation Grant Award unless the Institute's approval declines to continue eligibility during the pendency of the delinquency.		

Rule § 703.14 Termination, Extension, and Close Out of Grant Contracts

- (a) The termination date of a Grant Contract shall be the date stated in the Grant Contract, except:
- (1) The Chief Executive Officer may elect to terminate the Grant Contract earlier because the Grant Recipient has failed to fulfill contractual obligations, including timely submission of required reports or certifications;
- (2) The Institute terminates the Grant Contract because funds allocated to the Grant Award are reduced, depleted, or unavailable during the award period, and the Institute is unable to obtain additional funds for such purposes; or
- (3) The Institute and the Grant Recipient mutually agree to terminate the Grant Contract earlier.
- (b) If the Institute elects to terminate the Grant Contract pursuant to subsection (a)(1) or (2) of this section, then the Chief Executive Officer shall notify the Grant Recipient in writing of the intent to terminate funding at least 30 days before the intended termination date. The notice shall state the reasons for termination, and the procedure and time period for seeking reconsideration of the decision to terminate. Nothing herein restricts the Institute's ability to terminate the Grant Contract immediately or to seek additional remedies if justified by the circumstances of the event leading to early termination.
- (c) The Institute may approve the Grant Recipient's written request to extend the termination date of the Grant Contract to permit the Grant Recipient additional time to complete the work of the project.
- (1) A no cost extension may be granted only if the Grant Recipient is in good fiscal and programmatic standing.
- (2) The Grant Recipient may request a no cost extension no earlier than 180 days and no later than 30 days prior to the termination date of the Grant Contract.
 - (A) If a Grant Recipient does not request a no cost extension within the required timeframe, the Chief Executive Officer may approve the request for good cause. If a no cost extension request is approved under this subsection, the Chief Executive Officer must notify the Oversight Committee in writing and provide justification for the approval.
- (3) The Institute may approve one no cost extension, the duration of which may be no longer than six months from the termination date of the Grant Contract, unless the Institute finds that special circumstances justify authorizing additional time to complete the work of the project.
- (4) If the Institute approves the request to extend the termination date of the Grant Contract, then the termination date shall be amended to reflect the change.
- (5) Nothing herein prohibits the Institute and the Grant Recipient from taking action more than 180 days prior to the termination date of the Grant contract to extend the termination date of the Grant Contract. Approval of an extension must be supported by a finding of good cause and the Grant Contract shall be amended to reflect the change.
- (d) Within ninety (90) days after the termination of the Grant Contract, the Grant Recipient must submit a final Financial Status Report and final Grant Progress Report as well as any other required

reports as specified in the Grant Contract. For purposes of this rule, these reports shall be collectively referred to as "close out documents."

- (1) If the Grant Recipient has submitted the final Financial Status Report on or before the 30th day following the due date specified in §703.21(b), but has not submitted other close out documents, then the final reimbursement payment shall not be made until such other close out documents have been submitted and approved by the Institute. The Grant Recipient's failure to submit the Financial Status report within 30 days following the due date specified in §703.21(b) will waive reimbursement of project costs incurred during the reporting period.
- (2) Failure to submit all other close out documents within 180 days of the Grant Contract termination date shall result in the Grant Recipient being ineligible to receive new Grant Awards or continuation Grant Awards until such time that the close out documents are submitted unless the Institute waives the final submission of close out documents by the Grant Recipient.
- (A) Approval of the Grant Recipient's request to waive the submission of close out documents is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.
- (B) The Oversight Committee shall be notified in writing of the Grant Recipient's waiver request and the Chief Executive Officer's decision to approve or reject the waiver request.
- (C) Unless the Oversight Committee votes by a simple majority of members present and able to vote to overturn the Chief Executive Officer's decision regarding the waiver, the Chief Executive Officer's decision shall be considered final.
- (e) The Institute may make upward or downward adjustments to the Allowable Costs requested by the Grant Recipient within ninety (90) days following the receipt of the close out reports.
- (f) Nothing herein shall affect the Institute's right to disallow costs and recover Grant Award funds on the basis of a later audit or other review or the Grant Recipient's obligation to return Grant Award funds owed as a result of a later refund, correction, or other transaction.
- (g) Any Grant Award funds paid to the Grant Recipient in excess of the amount to which the Grant Recipient is finally determined to be entitled under the terms of the Grant Contract constitute a debt to the state. If not paid within a reasonable period after demand, the Institute may reduce the debt owed by:
- (1) Making an administrative offset against other requests for reimbursements;
- (2) Withholding advance payments otherwise due to the Grant Recipient; or
- (3) Other action permitted by law.

Rule § 703.20 Certification of Tobacco-Free Policy for Grant Recipients

To be eligible to receive a Grant Award, a Grant Recipient shall certify that the entity has adopted and enforces a Tobacco-free workplace policy.

- (1) A Tobacco-free workplace policy will comply with the certification required by this section if the policy is adopted by the Grant Recipient's board of directors, governing body, or similar and, at a minimum, includes provisions:
- (A) Prohibiting the use of all Tobacco products by all employees and visitors to the property owned, operated, leased, occupied, or controlled by the Grant Recipient. For purposes of the Tobacco-free workplace policy, the Grant Recipient may designate the property to which the policy applies, so long as the workplace policy encompasses all buildings and structures where the Grant Award project is taking place as well as the sidewalks, parking lots, walkways, and attached parking structures immediately adjacent, but only to the extent the Grant Recipient owns, leases or controls the building, sidewalks, parking lots and parking structures.
 - (B) Providing for and/or referring to Tobacco use cessation services for employees.
- (2) Upon request by a Grant Recipient and a showing of good cause, the Chief Executive Officer may authorize a waiver of compliance with this section. In the event that the requested waiver is necessary because Tobacco use is a required component of one or more research studies conducted at the entity, the Grant Recipient must specify the research project and location of the project. If approved, the waiver is effective only for the State fiscal year during which it was approved. CPRIT reserves the right to limit the waiver to a specific location or time period.
- (3) The certification and waiver requests addressed herein shall be submitted by the Grant Recipient via the Institute's electronic Grant Management System.

Rule § 703.21 Monitoring Grant Award Performance and Expenditures

- (a) The Institute, under the direction of the Chief Executive Officer, shall monitor Grant Awards to ensure that Grant Recipients comply with applicable financial, administrative, and programmatic terms and conditions and exercise proper stewardship over Grant Award funds. Such terms and conditions include requirements set forth in statute, administrative rules, and the Grant Contract.
- (b) Methods used by the Institute to monitor a Grant Recipient's performance and expenditures may include:
- (1) Financial Status Reports Review Quarterly financial status reports shall be submitted to the Institute within 90 days of the end of the state fiscal quarter (based upon a September 1 August 31 fiscal year). The Institute shall review expenditures and supporting documents to determine whether expenses charged to the Grant Award are:
- (A) Allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds; and
- (B) Adequately supported with documentation such as cost reports, receipts, third party invoices for expenses, or payroll information.
- (2) Timely submission of Financial Status Reports The Grant Recipient waives the right to reimbursement of project costs incurred during the reporting period if the financial status report for that quarter is not submitted to the Institute within 30 days of the FSR due date. Waiver of reimbursement of project costs incurred during the reporting period also applies to Grant Recipients that have received advancement of Grant Award funds.
- (A) For purposes of this rule, the "FSR due date" is 90 days following the end of the state fiscal quarter.
- (B) The Chief Executive Officer may approve a Grant Recipient's request to defer submission of the reimbursement request for the current fiscal quarter until the next fiscal quarter if, on or before the original FSR due date, the Grant Recipient submits a written explanation for the Grant Recipient's inability to complete a timely submission of the FSR.
- (C) Notwithstanding subsection (2), in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding FSR(s). The Program Officer's approval may cover more than FSR and more than one fiscal quarter.
- (D) In order to receive disbursement of grant funds, the most recently due FSR must be approved by CPRIT.
- (3) Grant Progress Reports The Institute shall review Grant Progress Reports to determine whether sufficient progress is made consistent with the scope of work and timeline set forth in the Grant Contract.
- (A) The Grant Progress Reports shall be submitted at least annually, but may be required more frequently pursuant to Grant Contract terms or upon request and reasonable notice of the Institute.

- (B) The annual Grant Progress Report shall be submitted within sixty (60) days after the anniversary of the effective date of the Grant Contract. The annual Grant Progress Report shall include at least the following information:
- (i) An affirmative verification by the Grant Recipient of compliance with the terms and conditions of the Grant Contract;
- (ii) A description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, including information, data, and program metrics regarding the achievement of project goals and timelines;
- (iii) The number of new jobs created and the number of jobs maintained for the preceding twelve month period as a result of Grant Award funds awarded to the Grant Recipient for the project;
- (iv) An inventory of the equipment purchased for the project in the preceding twelve month period using Grant Award funds;
- (v) A verification of the Grant Recipient's efforts to purchase from suppliers in this state more than 50 percent goods and services purchased for the project with grant funds;
 - (vi) A Historically Underutilized Businesses report;
- (vii) Scholarly articles, presentations, and educational materials produced for the public addressing the project funded by the Institute;
- (viii) The number of patents applied for or issued addressing discoveries resulting from the research project funded by the Institute;
- (ix) A statement of the identities of the funding sources, including amounts and dates for all funding sources supporting the project;
- (x) A verification of the amounts of Matching Funds dedicated to the research that is the subject of the Grant Award for the period covered by the annual report, which shall be submitted pursuant to the timeline in § 703.11;
 - (a) <u>In order to receive disbursement of grant funds, the most recently due verification of the amount of Matching Funds must be approved by CPRIT.</u>
- (xi) All financial information necessary to support the calculation of the Institute's share of revenues, if any, received by the Grant Recipient resulting from the project; and
 - (xii) A single audit determination form.
- (C) Notwithstanding subsection (B), in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding reports. The Program Officer's approval may cover more than one report and more than one fiscal quarter.
- (C) In addition to annual Grant Progress Reports, a final Grant Progress Report shall be filed no more than ninety (90) days after the termination date of the Grant Contract. The final Grant Progress Report shall include a comprehensive description of the Grant Recipient's progress made toward completing

the scope of work specified by the Grant Contract, as well as other information specified by the Institute.

- (D) The Grant Progress Report will be evaluated by a grant manager pursuant to criteria established by the Institute. The evaluation shall be conducted under the direction of the Chief Prevention Officer, the Chief Product Development Officer, or the Chief Scientific Officer, as may be appropriate. Required financial reports associated with the Grant Progress Report will be reviewed by the Institute's financial staff.
 - (i) <u>In order to receive disbursement of grant funds, the final progress report must be</u> approved by CPRIT.
- (E) If the Grant Progress Report evaluation indicates that the Grant Recipient has not demonstrated progress in accordance with the Grant Contract, then the Chief Program Officer shall notify the Chief Executive Officer and the General Counsel for further action.
- (i) The Chief Program Officer shall submit written recommendations to the Chief Executive Officer and General Counsel for actions to be taken, if any, to address the issue.
- (ii) The recommended action may include termination of the Grant Award pursuant to the process described in §703.14 of this chapter (relating to Termination, Extension, and Close Out of Grant Contracts).
- (F) If the Grant Recipient fails to submit required financial reports associated with the Grant Progress Report, then the Institute financial staff shall notify the Chief Executive Officer and the General Counsel for further action.

(G) In order to receive disbursement of grant funds, the most recently due progress report must be approved by CPRIT.

- (G) If a Grant Recipient fails to submit the Grant Progress Report within 60 days of the anniversary of the effective date of the Grant Contract, then the Institute shall not disburse any Grant Awards funds as reimbursement or advancement of Grant Award funds until such time that the delinquent Grant Progress Report is filed approved.
- (H) In addition to annual Grant Progress Reports, Product Development Grant Recipients shall submit a Grant Progress Report at the completion of specific tranches of funding specified in the Award Contract. For the purpose of this subsection, a Grant Progress Report submitted at the completion of a tranche of funding shall be known as "Tranche Grant Progress Report."
- (i) The Institute may specify other required reports, if any, that are required to be submitted at the time of the Tranche Grant Progress Report.
- (ii) Grant Funds for the next tranche of funding specified in the Grant Contract shall not be disbursed until the Tranche Grant Progress Report has been reviewed and approved pursuant to the process described in this section.
- (4) Desk Reviews The Institute may conduct a desk review for a Grant Award to review and compare individual source documentation and materials to summary data provided during the Financial Status

Report review for compliance with financial requirements set forth in the statute, administrative rules, and the Grant Contract.

- (5) Site Visits and Inspection Reviews The Institute may conduct a scheduled site visit to a Grant Recipient's place of business to review Grant Contract compliance and Grant Award performance issues. Such site visits may be comprehensive or limited in scope.
- (6) Audit Reports The Institute shall review audit reports submitted pursuant to §703.13 of this chapter (relating to Audits and Investigations).
- (A) If the audit report findings indicate action to be taken related to the Grant Award funds expended by the Grant Recipient or for the Grant Recipient's fiscal processes that may impact Grant Award expenditures, the Institute and the Grant Recipient shall develop a written plan and timeline to address identified deficiencies, including any necessary Grant Contract amendments.
 - (B) The written plan shall be retained by the Institute as part of the Grant Contract record.
- (c) All required Grant Recipient reports and submissions described in this section shall be made via an electronic grant portal designated by the Institute, unless specifically directed to the contrary in writing by the Institute.
- (d) The Institute shall document the actions taken to monitor Grant Award performance and expenditures, including the review, approvals, and necessary remedial steps, if any.
- (1) To the extent that the methods described in subsection (b) of this section are applied to a sample of the Grant Recipients or Grant Awards, then the Institute shall document the Grant Contracts reviewed and the selection criteria for the sample reviewed.
- (2) Records will be maintained in the electronic Grant Management System as described in §703.4 of this chapter (relating to Grants Management System).
- (e) The Chief Compliance Officer shall be engaged in the Institute's Grant Award monitoring activities and shall notify the General Counsel and Oversight Committee if a Grant Recipient fails to meaningfully comply with the Grant Contract reporting requirements and deadlines, including Matching Funds requirements.
- (f) The Chief Executive Officer shall report to the Oversight Committee at least annually on the progress and continued merit of each Grant Program funded by the Institute. The written report shall also be included in the Annual Public Report. The report should be presented to the Oversight Committee at the first meeting following the publication of the Annual Public Report.
- (g) The Institute may rely upon third parties to conduct Grant Award monitoring services independently or in conjunction with Institute staff.



MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS

From: NED HOLMES, CHAIR, BOARD GOVERNANCE SUBCOMMITTEE

Subject: INTENTION TO RECOMMEND APPROVAL OF FINAL ORDER

ADOPTING CHANGES TO ADMINISTRATIVE RULES

NOVEMBER 4, 2015

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee approve a final order adopting changes to 25 T.A.C. Chapter 703. The proposed amendments relate to indirect cost payments by prevention grantees and required compliance training. The rule changes were published in the *Texas Register* on September 25, 2015, and made available for public comment for 30 days. The Board Governance Subcommittee reviewed the final order with CPRIT's General Counsel.

Discussion

The change to be adopted for § 703.12 clarifies that prevention grantees may spend up to five percent of their grant funds on indirect costs. This change was suggested by the Prevention Program staff in response to concerns raised by potential applicants. The new rule § 703.22 addresses required grantee compliance training.

Three comments on the proposed rule changes were received from the public. Two comments support the proposed change to § 703.12 permitting prevention grantees to spend up to five percent of grant funds on indirect costs and offer no suggested changes. The third comment seeks clarification regarding the application of the proposed change in § 703.12 to existing grants and whether additional grant funds would be added to awards for indirect costs. No changes to the rules as proposed are necessary in response to the comments received.

The Board Governance Subcommittee has reviewed the final order and recommends approval by the Oversight Committee. The final order will become effective 20 days after it is filed with the Secretary of State.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendments to § 703.12 and new rule, § 703.22. The proposed amendments and new rule for Chapter 703 were published in the September 25, 2015, issue of the *Texas Register* (40 TexReg 6573).

Reasoned Justification

Texas Health and Safety Code § 102.203(c) limits the amount of grant funds cancer research grantees may spend on indirect costs to five percent of the total award. Currently, the rule expressly limits research grantees spending on indirect costs, but does not address prevention grant funds. The proposed amendment to § 703.12 limits prevention grantees to the same five percent cap on indirect costs paid for with grant funds.

The proposed new rule § 703.22 requires new and current grantees to complete annual compliance training while they have an active CPRIT grant. The Institute's Chief Compliance Officer will develop the training, which may include online webinars. CPRIT may withhold grant reimbursement if a grantee fails to complete the required training.

Summary of Public Comments and Staff Recommendations

The Institute accepted public comments in writing and by fax through October 26, 2015.

No comments were received regarding new rule § 703.22. CPRIT received comments from the Ms. Linda Robinson, Dr. Theresa Byrd, and UT Southwestern Medical Center (UTSW) regarding the amendment to § 703.12. Ms. Robinson and UTSW support allowing prevention grantees to spend up to five percent of grant funds on indirect costs because the change is consistent with the limit on cancer research grants and it would relieve a portion of the administrative burden associated with prevention grants. Dr. Byrd did not suggest changes to the proposed amendment, but sought clarification regarding whether the rule change would apply to current grants and whether CPRIT would add more money to existing prevention grants for indirect costs. The rule change will apply to prevention grantees prospectively. Grantees are not entitled to additional grant funds based on the rule change, but permits prevention grantees to spend up to five percent of approved grant funds for administrative expenses.

The amendments to Chapter 703 will be adopted as published in the September 25, 2015, edition of the *Texas Register* and will not be republished.

Certification

The Institute hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

To be filed with the Office of Secretary of State on November 20, 2015.

RULE § 703.12 Limitation on Use of Funds

- (a) A Grant Recipient may use Grant Award funds only for Cancer Research and Cancer Prevention projects consistent with the purpose of the Act, and in accordance with the Grant Contract. Grant Award funds may not be used for purposes other than those purposes for which the grant was awarded. The Institute may require a Grant Recipient to repay Grant Award funds if the Grant Recipient fails to expend the Grant Award funds in accordance with the terms and conditions of the Grant Contract and the provisions of this chapter.
- (b) Grant Award funds must be used for Authorized Expenses.
- (1) Expenses that are not authorized and shall not be paid from Grant Award funds, include, but are not limited to:
 - (A) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.
 - (B) Contributions to a contingency reserve or any similar provision for unforeseen events.
 - (C) Contributions and donations made to any individual or organization.
- (D) Costs of entertainment, amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.
- (E) Costs relating to food and beverage items, unless the food item is related to the issue studied by the project that is the subject of the Grant Award.
- (F) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.
 - (G) An honorary gift or a gratuitous payment.
 - (H) Interest and other financial costs related to borrowing and the cost of financing.
- (I) Legislative expenses such as salaries and other expenses associated with lobbying the state or federal legislature or similar local governmental bodies, whether incurred for purposes of legislation or executive direction.
 - (J) Liability insurance coverage.
- (K) Benefit replacement pay or legislatively-mandated pay increases for eligible general revenuefunded state employees at Grant Recipient state agencies or universities.
 - (L) Professional association fees or dues for the Grant Recipient or an individual.
- (M) Promotional items and costs relating to items such as T-shirts, coffee mugs, buttons, pencils, and candy that advertise or promote the project or Grant Recipient.
- (N) Patient support services costs relating to services such as personal care items and financial assistance for low-income clients.

- (2) Additional guidance regarding Authorized Expenses for a specific program may be provided by the terms of the Grant Contract and by the Uniform Grant Management Standards (UGMS) adopted by the Comptroller's Office. If guidance from UGMS on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, Texas Health and Safety Code, or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.
- (3) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Authorized Expense.
- (c) A Grant Recipient of Grant Award funds for a Cancer Research <u>or Cancer Prevention</u> project may not spend more than five percent (5%) of the Grant Award funds for Indirect Costs.
- (d) The Institute may not award more than five percent (5%) of the total Grant Award funds for each fiscal year to be used for facility purchase, construction, remodel, or renovation purposes during any year. Any Grant Award funds that are to be expended by a Grant Recipient for facility purchase, construction, remodel, or renovations are subject to the following conditions:
- (1) The use of Grant Award funds must be specifically approved by the Chief Executive Officer with notification to the Oversight Committee;
- (2) Grant Award funds spent on facility purchase, construction, remodel, or renovation projects must benefit Cancer Prevention and Research;
- (3) If Grant Award funds are used to build a capital improvement, then the state retains a lien or other interest in the capital improvement in proportion to the percentage of the Grant Award funds used to pay for the capital improvement. If the capital improvement is sold, then the Grant Recipient agrees to repay to the state the Grant Award funds used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale.
- (e) The Institute may not award more than ten percent (10%) of the money awarded from the Cancer Prevention and Research Fund or from the proceeds of bonds issued on behalf of the Institute to be used for Cancer Prevention and Control programs during any year. Grant Awards for Cancer Prevention research projects shall not be counted toward the Grant Award amount limit for Cancer Prevention and Control Programs. For purposes of this subsection, the Institute is presumed to award the full amount of funds available.

RULE §703.22 Required Training for Grant Recipients

- (a) The Institute, under the direction of the Chief Compliance Officer, shall create a compliance training program for Grant Recipients addressing applicable financial, administrative, and programmatic requirements related to proper stewardship over Grant Award funds, including grant reporting.
- (b) Initial Grant Recipient training program A Grant Recipient that is approved for a Grant Award for the first time on or after September 1, 2015, shall complete an initial compliance training program. For purposes of this subsection, a Grant Recipient that has received at least one Grant Award prior to September 1, 2015, is not required to complete the initial compliance training program.
- (1) The Chief Compliance Officer shall design the initial compliance training program.
- (2) The Grant Recipient must complete the initial compliance training program prior to receiving disbursement of Grant Award funds, unless the Chief Compliance Officer finds good cause to disburse grant funds in advance of completing the initial compliance training program.
- (3) Nothing herein prohibits the Chief Compliance Officer from requiring a Grant Recipient to complete the initial compliance training program.
- (c) Annual Grant Recipient training program All Grant Recipients shall complete an annual compliance training program by November 1, 2016, and then by November 1 of each year thereafter that the Grant Recipient has at least one active Grant Award.
- (1) The Chief Compliance Officer shall design the annual compliance training program.
- (2) The Institute shall withhold disbursement of Grant Award funds if the Grant Recipient fails to complete the annual compliance training program by November 1, unless the Chief Compliance Officer finds good cause to disburse grant funds in advance of completing the annual compliance training program.
- (d) Grant Recipient personnel required to attend training The Grant Recipient's Authorized Signing Official and at least one other individual employed by the Grant Recipient must attend the trainings required by this rule.
- (1) Upon a finding of good cause, the Chief Compliance Officer may allow the Grant Recipient to substitute another employee to attend a required training in place of the Authorized Signing Official.
- (2) In the event that the Authorized Signing Official designated by the Grant Recipient changes on or after November 1, 2016, and the new Authorized Signing Official has not completed the annual compliance training program, the new Authorized Signing Official shall complete the annual compliance training program within 60 days of change. Failure to do so may result in the withholding of Grant Award funds until the training is completed.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS ADVISORY COMMITTEE ON CHILDHOOD CANCERS CHARTER

BACKGROUND

Texas Health and Safety Code §102.155 establishes the ad hoc committee of experts to address childhood cancers, known as the Advisory Committee on Childhood Cancers ("ACCC"), and to advise the Cancer Prevention and Research Institute of Texas ("Institute"). This Charter ("ACCC Charter"), adopted by the ACCC members and approved by the Oversight Committee of the Cancer Prevention and Research Institute of Texas ("Oversight Committee") on November 19, 2014, supersedes any other documents relating to the ACCC.

PURPOSE

The primary purpose of the ACCC is to advise the Oversight Committee and each of the Scientific Research and Prevention Programs Committees regarding opportunities for innovative research on the prevention, control, and cure of childhood cancers, opportunities for implementation of prevention and survivorship programs, and current information regarding treatment programs in Texas designed to prevent and control childhood cancers.

COMPOSITION

The ACCC shall be composed of at least ten members appointed by the Oversight Committee. Of the ten members, at least two members shall be patient advocates. Additionally, the Oversight Committee should consider individuals with research and/or clinical expertise in the care of children with cancer and/or knowledge and expertise in laboratory, translational, and clinical research relevant to childhood cancer biology, causes of childhood cancer, childhood cancer treatment and care delivery, and the long-term care of childhood cancer survivors when making appointments to the ACCC. Institutions with a large patient population and institutions with significant non-clinical research strengths may have more than one member on the ACCC. Current institutions that hold this status include: Cook Children's Hospital, The University of Texas M.D. Anderson Cancer Center, Texas Children's Cancer Center, Texas Tech University Health Sciences Center, The University of Texas Health Science Center at San Antonio, and The University of Texas Southwestern Medical Center. The ACCC may add new member institutions as membership criteria are met. Each member institution must identify a lead

member, and only the lead member will have voting privileges on the committee.

ACCC members shall serve twothree-year terms, at the end of which the Oversight Committee may renew the appointment of the ACCC member or appoint a new member. The <u>first</u> twothree-year terms of the ACCC <u>members that were active on November 14, 2014 will expire on November 13, 2017, and are subject to renewal. already constituted at the time the ACCC Charter is approved shall begin on the day after approval.</u>

If an ACCC member is unable to complete his or her term, the Oversight Committee shall appoint someone to fulfill the remainder of the term. Any member that does not participate in at least fifty percent of committee meetings will be replaced, and another individual from the member's institution will be appointed by the presiding officer of the Oversight Committee.

ELECTION OF OFFICERS

The ACCC Chairperson, Vice-Chairperson, and Secretary shall <u>serve a term not to exceed three years, and</u> be elected by a majority of ACCC members present and able to vote at the first regular meeting held with a quorum of members present. Thereafter, the election shall take place at the first meeting held on or after September 1. The term of an officer shall not extend longer than the officer's term on the ACCC. The Vice-Chairperson will succeed the Chairperson once <u>his/her term has expired.</u>

MEETINGS AND QUORUM

The ACCC shall meet as often as deemed necessary by the ACCC Chairperson. At a minimum, the ACCC shall meet annually to compose a report to send to the Oversight Committee and to conduct any other business required by this Charter, statutes, or administrative rules. Communication by email can be used to advance the work of the committee between formal meetings.

A meeting of the ACCC requires a quorum of members. Such meeting may take place in person or by teleconference. A quorum exists when at least a majority of appointed members of the ACCC are present or available via telephone. If there is an even number of currently appointed members, then half that number plus one member constitutes a quorum.

The Secretary or his/her designate shall record the minutes for each ACCC meeting. The Secretary shall forward the final meeting minutes to the Institute's Chief Executive Officer for retention and distribution to the Oversight Committee members.

An office copy of the ACCC meeting minutes will be retained at CPRIT headquarters and available to the public on request. The Institute's CEO will distribute the minutes to the

Oversight Committee members on or before the Oversight Committee meeting following the date that the minutes were submitted to CPRIT.

DUTIES AND RESPONSIBILITIES

The ACCC shall submit a written report, at least annually, to the Oversight Committee regarding the work undertaken by the ACCC for the previous year and the ACCC's recommendations for the Institute. The report shall be submitted by the end of each calendar year to the Oversight Committee's Presiding Officer for distribution to the Oversight Committee.

The ACCC Chairperson shall present the report at the first regular meeting of the Oversight Committee following the submission of the written report. If the Chairperson is unable to attend, then the Vice-Chairperson or other designee may present the report.

The report shall inform the Oversight Committee regarding:

- Cancer research relating to childhood cancer including the state of research and promising areas of research such as basic science, translational science, clinical trials, and health care delivery;
- Cancer prevention programs relating to childhood cancer including the state of cancer
 prevention programs, the most innovative approaches to cancer prevention programs, the
 most effective approaches to delivering cancer prevention programs, and the most
 promising cancer prevention program opportunities, including design and initial
 implementation of programs, execution of programs, and researching of effective
 programs;
- Information on the control and cure of childhood cancers; and
- Other issues that will advance the goals and mission of the Institute.

Additionally, the ACCC may provide to the Oversight Committee and to each Scientific Research and Prevention Programs Committee on-going advice, input and support related to the development of programs that will have a lasting impact on childhood cancer research and prevention efforts in Texas.

OTHER DUTIES

In addition to duties and responsibilities stated herein, the Oversight Committee's Presiding Officer may authorize additional, official duties of the ACCC.

The ACCC retains the ability to make, alter, amend, or repeal the ACCC Charter in order to best conduct business. Proposed changes to the ACCC Charter shall be made pursuant to a majority vote of the ACCC members. Proposed changes are final once approved by a vote of the Oversight Committee.

CHARTER APPROVAL

As reflected by the signatures of the ACCC Chairperson and Oversight Committee's Presiding Officer, the ACCC was adopted and approved in compliance with the process specified herein on the dates stated below.

Adopted by the ACCC	Approved by the Oversight Committee		
	William Rice, M.D.		
Chair, ACCC	Presiding Officer, Oversight Committee		
Date:	Date:		



MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS

FROM: HEIDI MCCONNELL, CHIEF OPERATING OFFICER

SUBJECT: CHIEF OPERATING OFFICER REPORT

DATE: NOVEMBER 11, 2015

CPRIT Financial Overview for FY 2015, Quarter 4

FY 2015, Quarter 4 Operating Budget

As of the end of August 2015, CPRIT has expended or encumbered approximately \$18 million, or 88 percent, of the agency administration budget between the Indirect Administration and Grant Review and Award Operations strategies out of \$20.3 million budgeted for the year. The primary items of expenditure remain staff salaries and service contracts, particularly the contract with SRA International that provides pre- and post-award grant management support services, including processing peer review honoraria and travel for the peer review meetings.

During this quarter, CPRIT received \$9,327 in revenue sharing payments which was deposited into the General Revenue Fund (0001). Total revenue sharing payments received for the year were \$46,774.

FY 2015, Quarter 4 Performance Measures

In October 2015, CPRIT reported to the LBB on the two output measures that have quarterly reporting requirements as well as the other four measures that are reported only annually. CPRIT met or exceeded five of the six performance measures that it is required to report. The one measure that was not achieved was Number of Entities Relocating to Texas because the target was set at 7 entities but 5 entities actually relocated to Texas during the year.

Debt Issuance History

The Texas Public Finance Authority issued \$244.6 million in commercial paper notes on CPRIT's behalf during FY 2015. The total debt issued from agency inception through the end of August was approximately \$793.4 million.

Activities Since September 1, 2015

CPRIT has completed and submitted the agency's Annual Financial Report due to the Comptroller's Office by November 20. The agency's financial report is incorporated in the state's *Comprehensive Annual Financial Report*.

CPRIT is in the midst of its annual financial audit performed by McConnell & Jones LLP. As part of this audit, the auditor verifies that the financial information in the agency's Annual Financial Report is correct and that the agency is complying with state law, agency rules, and agency operating procedures. The audit report will be issued in December and presented to the

Audit Subcommittee before being submitted to the Comptroller's Office by the December 20 deadline.

The Legislative Budget Board published FY 2016 Operating Budget instructions on November 10. The due date for Operating Budget Instructions to the LBB is December 1.

Cancer Prevention and Research Institute of Texas Quarterly Financial Report As of August 31, 2015

Ind	ire	ct	Δd	lmini	stration	(R 1 1)

							Actual Expenditures &				
			2015			% of Total	of Total Grant Encumbrances		R	emaining	Percent
		Αp	propriated	2	015 Budgeted	Budget		(FYTD)		Budget	Expended
1001	Salaries and Wages	\$	1,571,528	\$	1,571,528		\$	1,153,786		417,742	73%
1002	Other Personnel Costs		50,000		50,000			17,544		32,456	35%
2001	Professional Fees and Services		992,290		992,290			715,925		276,365	72%
2003	Consumable Supplies		25,750		25,750			11,875		13,875	46%
2004	Utilities		63,648		63,648			50,779		12,869	80%
2005	Travel		24,176		24,176			29,733		(5,557)	123%
2006	Rent - Building		181,875		181,875			167,073		14,802	92%
2007	Rent-Machine and Other		29,644		29,644			18,112		11,532	61%
2009	Other Operating Expenses		456,500		456,500			225,907		230,593	49%
5000	Capital		979,514		979,514			860,392		119,122	0%
	Subtotal - Indirect Administration (B.1.1.)	\$	4,374,925	\$	4,374,925	1.46%	\$	3,251,127	\$	1,123,798	74%

Grant Review and Award Operations (A.1.3.)

		Aŗ	2015 opropriated	2015 Budgeted	% of Total Budget		al Expenditures & at Encumbrances (FYTD)		Remaining Budget	Percent Expended
1001	Salaries and Wages	\$	2,654,617	2,654,617		\$	2,270,963	\$	383,654	86%
1002	Other Personnel Costs		100,000	100,000			40,027		59,973	0%
2001	Professional Fees and Services		13,278,211	13,278,211			12,408,012		870,199	93%
2003	Consumable Supplies		-	-			-		-	0%
2005	Travel		35,000	35,000			38,867		(3,867)	111%
2006	Rent - Building		32,400	32,400			34,455		(2,055)	106%
2007	Rent-Machine and Other		5,013	5,013			3,036		1,977	61%
2009	Other Operating Expenses		-	-			-		-	0%
	Subtotal - Grant Operations (A.1.3.)	Ś	16 105 241	\$ 16 105 241	5 37%	Ś	14 795 360	ς	1 309 881	92%

_			
G	ra	n	T.S

	Grants							
		2015 Appropriated	2	015 Budgeted	% of Total Budget	tual Expenditures & ant Encumbrances (FYTD)	Remaining Budget	Percent Expended
4000	Grants - Prevention (A.1.2)	\$ 27,961,891	\$	27,961,891		\$ 27,890,646	\$ 71,245	100%
4000	Grants - Research (A.1.1.)	251,378,010	\$	251,378,010		249,449,488	\$ 1,928,522	99%
	Subtotal - Grants	\$ 279,339,901	\$	279,339,901	93.17%	\$ 277,340,134	\$ 1,999,767	99%
	Grand Totals	\$ 299,820,067	\$	299,820,067	100.00%	\$ 295,386,621	\$ 4,433,446	99%

^{* 2015} Appropriated and budgeted includes a transfer from strategy A.1.1. (Research) into strategies A.1.3. (Grant Operations) and B.1.1. (Indirect Administration) approved by the Legislative Budget Board pursuant to the 2014-15 General Appropriation Act, CPRIT Rider 5, Transfer Authority.

Cancer Prevention and Research Institute of Texas Cancer Prevention and Research Institute Fund Account - 5136 As of August 31, 2015

		08/01/2015 thru 08/31/2015		
Beginning Balance : 08/01/2015			\$	600,506
Increases:				
(1) (2)	\$		\$	-
Total Increases	\$		\$	600,506.00
Reductions:				
Expenditures - Appropriated	\$	-	\$	-
	\$ \$	-	\$	-
	\$	-	\$	-
Total Reductions	\$	-	\$	-
Ending Balance, 08/31/2015			\$	600,506.00

Note: (1) The Institute received a settlement from the Texas Cancer Coalition (TCC). This amount represents the final distribution and transfer of all funds (\$303,877) from the TCC which ceased operations in May 2013. These funds are in the State Treasury but are not appropriated to CPRIT. The beginning balance reflects the transfer of all TCC funds.

Account 5136 Page 2 of 5

Cancer Prevention and Research Institute of Texas License Plate Trust Fund Account - 0802 As of August 31, 2015

	1/2015 thru 3/31/2015	AY 15 Year to Date as of 08/31/2015		
Beginning Balance : 08/01/2015		\$	15,080.00	
Increases: (1) License Plate Revenue Received	\$ 1,105.47	\$	13,622.49	
Total Increases	\$ 1,105.47	\$	28,702.49	
Reductions: Expenditures - Appropriated	\$ 0.00	\$	0.00	
Total Reductions	\$ 0.00	\$	0.00	
Ending Balance, 08/31/2015		\$	28,702.49	

Note:

Cancer Prevention and Research Institute of Texas Appropriated Receipts - 666 As of August 31, 2015

		01/2015 thru 08/31/2015	ear to Date as of 08/31/2015
Beginning B	alance : 08/01/2015		\$ 24,000.00
Increases:			
(1)	Product Development Application Fees Received	\$ -	\$ 15,000.00
(2)	Appropriated Receipts applied to payments	\$ -	\$ 98.50
(3)	Conference Registration Fees	\$ 42,750.00	\$ 62,102.00
(4)	Conference Registration Fees-Credit Card	\$ 1,201.95	\$ 1,745.63
Total Increas	ses	\$ 43,951.95	\$ 78,946.13
Reductions:			
	Expenditures - Appropriated		\$ (39,098.50)
		\$ -	\$ -
		\$ -	\$ -
Total Reduc	tions	\$ -	\$ (39,098.50)
Ending Bala	nce, 08/31/2015		\$ 63,847.63

Cancer Prevention and Research Institute of Texas General Revenue Fund Account - 0001 As of August 31, 2015

		08/01/2015 thru 08/31/2015		ear to Date as of 08/31/2015
Beginning Ba	lance : 08/01/2015		\$	1,000.00
Increases:				
(1)	Revenue Sharing / Royalties	\$ 8,327.24	\$	45,773.71
Total Increase	es	\$ 8,327.24	\$	46,773.71
Reductions:				
	Expenditures - Appropriated	\$ -	\$	-
	Sweep Account	\$ (8,327.24)	\$	(46,773.71)
		\$ -	\$	-
Total Reduction	ons	\$ (8,327.24)	\$	(46,773.71)
Ending Baland	ce, 08/31/2015		\$	-

Note:

Cancer Prevention and Research Institute of Texas FY 2015, Quarter 4 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	400,000	178,669	165,145	175,123	113,906	632,843	158.21%
Number of Entities Relocating to TX for Cancer Research Related Projects	7.00	0.00	1.00	1.00	3.00	5.00	71.43%
Percentage of Texas Regions with Cancer Prevention Services and Activities Initiated	100%	N/A	N/A	N/A	N/A	100%	100.00%
Annual Age-adjusted Cancer Mortality Rate	176.5	N/A	N/A	N/A	N/A	156.8	88.84%
Number of Published Articles on CPRIT- Funded Research Projects	400	N/A	N/A	N/A	N/A	1,092	273.00%
Number of New Jobs Created and Maintained	200	N/A	N/A	N/A	N/A	2,718	1359.00%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities

CPRIT grantees deliver these education and clinical services throughout the year, so the reported number of people served is not allocated evenly for each fiscal quarter.

Number of Entities Relocating to TX for Cancer Research Related Projects

This output is dependent on the number of companies applying for CPRIT Company Relocation Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas.

Annual Age-adjusted Cancer Mortality Rate

The rate calculation is affected by annual population adjustments. The calculation for 2015 is based on the age-adjusted mortality rate for all malignant cancer, males and females combined, for 2013. The rate is per 100,000 people and is age-adjusted to the 2000 US Standard population standard. The population counts used to calculate cancer mortality rates are supplied by the National Center for Health Statistics with support from the NCI. These population counts are based on estimates produced by the US Census Bureau's Population Estimates Program and are adjusted annually.

Number of Published Articles on CPRIT- Funded Research Projects

CPRIT used historical experience from the grant awards in its portfolio at the time the projection was developed. That portfolio was smaller than it is now. With more than 400 active grants in its portfolio, this reported number of published articles in academic and product development research may be a more realistic target for this measure. CPRIT will verify the reporting methodology grantees are following through its compliance monitoring program.

Number of New Jobs Created and Maintained

CPRIT used historical experience from the grant awards in its portfolio at the time the projection was developed. That portfolio was smaller than it is now. With more than 400 active grants in its portfolio, this reported number of new jobs created and jobs maintained in academic and product development research projects may be a more realistic target for this measure. CPRIT will verify the reporting methodology grantees are following through its compliance monitoring program.

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Aı	mount Issued		ount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	\$225,000,000	September 9, 2009	\$	9,100,000			Commercial Paper Notes	Series A, Taxable		
2010		September 9, 2009	\$	3,600,000			Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	\$	63,800,000			Commercial Paper Notes	Series A, Taxable		
2010		August 26, 2010	\$	148,500,000			Commercial Paper Notes	Series A, Taxable		
					\$	225,000,000				
2011	\$ 225,000,000	September 7, 2010	\$	11,800,000			Commercial Paper Notes	Series A, Taxable		
2011	\$ 223,000,000	August 10, 2011		50,775,000			G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True
2011		August 10, 2011	Y	30,773,000			G.O. DONGS	Tuxuble Series 2011	ar amount of new money	Interest Cost 4.0144%
2011		August 10, 2011	\$	232,045,000			G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded \$233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
					\$	62,575,000				
2012	\$300,000,000	September 7, 2011	Ś	3,200,000			Commercial Paper Notes	Series A, Taxable		
2012	\$ 300,000,000	December 8, 2011		3,200,000			Commercial Paper Notes	Series A, Taxable		
2012		March 2, 2012		12,300,000			Commercial Paper Notes	Series A, Taxable		
2012		June 21, 2012		15,000,000			Commercial Paper Notes	Series A, Taxable		
2012		,		42,000,000			Commercial Paper Notes	Series A, Taxable		
2012		August 10, 2012	٧	42,000,000	\$	75,700,000	commercial raper Notes	Jeries A, Taxable		
					7	73,700,000				
2013	\$300,000,000		\$	9,600,000			Commercial Paper Notes	Series A, Taxable		
2013		May 16,2013	\$	13,400,000			Commercial Paper Notes	Series A, Taxable		
					\$	23,000,000				
2014	\$ 300,000,000	November 22, 2013	Ś	55,200,000			Commercial Paper Notes	Series A, Taxable		
2014	7	,	Ś	47,000,000			Commercial Paper Notes	Series A, Taxable		
2014		June 17, 2014	\$	60,300,000			Commercial Paper Notes	Series A, Taxable		
2014		•	\$	233,280,000			G.O.Bond (Refunding	Taxable Series 2014	Par amount of refunding; Refunded	Fixed Rate Bonds All-In-True
		• •	•				Bonds)		\$237.88M of GOCP CPRIT Series A	Interest Cost 3.327184%
					\$	162,500,000	-			
2015	\$ 300,000,000	November 5, 2014	Ś	57,600,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
2015	, , , , , , , , , , , , , , , , , , , ,	April 29, 2014	т	112,000,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
2015		June 26, 2015	\$	75,000,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
		,		-,,	\$	244,600,000		,		
					·					
TOTAL ISSU	JED TO DATE				\$	793,375,000				

¹The weighted average interest rate for Commercial Paper Notes maturing in FY 2015 = 0.16%.



MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: VINCE BURGESS, CHIEF COMPLIANCE OFFICER

SUBJECT: CHIEF COMPLIANCE OFFICER REPORT

DATE: NOVEMBER 9, 2015

The Chief Compliance Officer is responsible for apprising the Oversight Committee and the Chief Executive Officer of institutional compliance functions and activities. The required reporting includes quarterly updates to the Oversight Committee on CPRIT's compliance with applicable laws, rules, and agency policies (T.A.C. § 701.7). In addition, the Chief Compliance Officer must inquire into and monitor the timely submission status of required grant recipient reports and notify the Oversight Committee and General Counsel of a grant recipient's failure to meaningfully comply with reporting deadlines.

Submission Status of Required Grant Recipient Reports

CPRIT Grant Compliance Specialists monitor the status of grantee reports that are currently due. A summary of missing reports is produced by CPRIT's grant management system (CGMS) every week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 530+ grants that are either active or wrapping up grant activities. Grantees submit between 12-15 reports each year per grant project. This means that CPRIT grantees should submit approximately 6,400 reports annually.

As of the most recent CGMS report (October 29, 2015), 17 required grantee reports from 8 entities have not been filed in the system by the set due date. In most cases, CPRIT does not disburse grant funds until the required reports are filed. In some instances, grantee institutions may be ineligible to receive a future award if required reports are not submitted. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to expeditiously resolve filing issues.

FSR Reviews

CPRIT's Grant Compliance Specialists have performed 433 second level reviews of grantee Financial Status Reports (FSRs) during the first two months of FY 2016. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Desk Reviews

A total of 61 desk reviews have been performed during the first two months of FY 2016 covering nine entities. Desk-based financial monitoring/reviews are conducted during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, procurement and contracting procedures and practices, current and past fiscal audits, subcontracting monitoring, and timeliness of required grantee report submission.

On-site Reviews

CPRIT compliance staff has performed five on-site reviews during the first two months of FY2016 covering product development research and prevention grant projects. On-site reviews may include examination of the grantee's financial and administrative operations, procurement and contracting policies and procedures, personnel policies and practices, payroll and timesheet policies, travel policies and records, and single audit compliance.

Single Audit Tracking

As part of ongoing monitoring efforts, grant compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend \$500,000 or more in CPRIT grant funds in the grantee's fiscal year must submit a single independent audit or have an audit performed according to Agreed Upon Procedures. The findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the recipient's fiscal year. Grant compliance specialists are currently working with seven grantees towards resolution of outstanding audit findings.

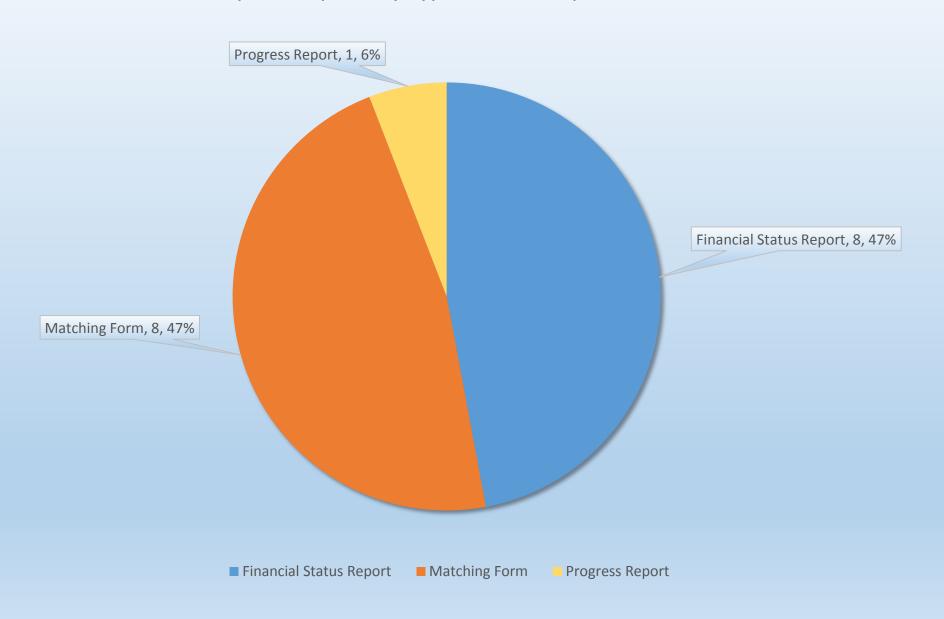
Training and Technical Assistance

Pursuant to the newly adopted rule (T.A.C. § 703.22) establishing mandatory compliance training requirements, the compliance program is developing a comprehensive training curriculum for new and current grantees. These training programs are expected to include a combination of on-site training and web-based training covering administrative rule requirements, reporting requirements, CGMS overview, and compliance program overview. Compliance staff will roll-out trainings for new and current grantees beginning January 2016.

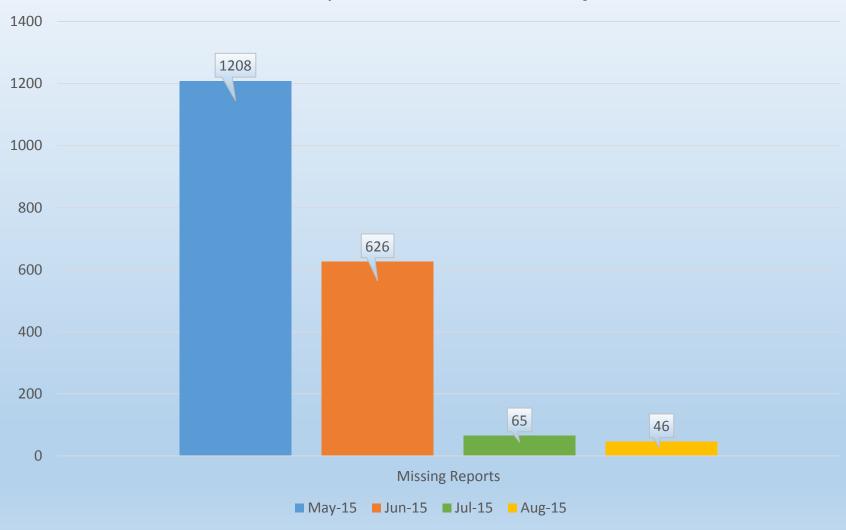
Grant Recipient Report Monitoring



Delinquent Reports by Type – CGMS Report 10/29/15



Grant Reports Reconciliation Project





MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: REBECCA GARCIA, PH.D. CHIEF PREVENTION AND

COMMUNICATIONS OFFICER

SUBJECT: COMMUNICATIONS UPDATE

DATE: NOV. 19, 2015

The following report provides an overview of the agency's communications activities from August 2015 through Nov. 19, 2015.

EARNED MEDIA

The communications team worked with and pitched individual publications and reporters to secure positive coverage for CPRIT, including coordinating an interview with Time Warner News' Capital Tonight regarding program priorities. We worked closely with Dallas Morning News reporter Bob Garrett on a story included below. Additionally, the communications team promoted the CPRIT conference through an op-ed by Pete Geren that appeared in the Austin American-Statesman, and an advance story in the Austin Business Journal.

Grant Awards Announcement: Following the Oversight Committee's approval, on Aug. 19, 2015, CPRIT distributed a press release to and pitched local, regional and national media announcing the awarding of seven academic research grants which resulted in some of the coverage represented below. Following the Oversight Committee's approval, on Sept. 10, 2015, CPRIT distributed another press release announcing five academic research grants, also represented in the coverage below.

Coverage: (Aug. 1, 2015 – Nov. 6, 2015)

- 9 articles featured CPRIT
- 79 additional articles mentioned CPRIT (stories primarily focused on work of grantees)

Coverage Highlights: (see clipped articles following report)

- Aug. 20, 2015, BioNews Texas, CPRIT Funds Recruitment of Top Scientists for Texas Academy
- Aug. 21, 2015, *Dallas Business Journal*, CPRIT Gives UT Southwestern \$13M in Grants For Recruitment
- Sept. 14, 2015, Austin American-Statesman, UT Gets \$6 Million to Hire Professor
- Sept. 14, 2015, *KVEO-TV (NBC Rio Grande Valley)*, CPRIT and the CAP Foundation Offering "See, Test & Treat" Program

- Sept. 18, 2015, *Austin American-Statesman*, Austin Biotech Firm Mirna Therapeutics Sets Terms For \$80 Million IPO
- Sept. 25, 2015, *Dallas Morning News*, Texas' Cancer-Research Agency Survived a Scandal. Now, it Hopes to Prove it's Working
- Oct. 2, 2015, *BioNews Texas*, UTHealth Receives \$5.7 Million in CPRIT Funding
- Oct. 3, 2015, San Angelo Standard-Times, Grant Funds Preventive Care Services for Breast Cancer
- Oct. 16, 2015, *Austin Business Journal*, CPRIT to Bring Product Innovators to Austin Conference
- Nov. 6, 2015, *Austin American-Statesman*, CPRIT Key in Making State Leader in Cancer Research

CPRIT 2015 Conference

Communications activities concentrated on planning and preparation for the Nov. 9-10, 2015, Innovations in Cancer Prevention and Research IV conference. More than 800 people attended the conference and over 400 abstracts were accepted for poster presentations. Videotaped interviews with various prevention, academic research and product development research grantees at the conference will be shared on CPRIT's website sometime soon.

Conference promotion included use of the CPRIT website, social media channels (#CPRIT2015 was our official hashtag), our listserv and media outreach. In October, the Austin Business Journal ran an advance story on the conference featuring a Q&A with Wayne.

CPRIT Messages

- The achievements report is being redesigned for FY 2016. A new report will be available after the November 19 Oversight Committee meeting.
- Texas House Speaker Joe Straus appeared at the CPRIT conference and had a positive message for attendees: "CPRIT is back...CPRIT is stronger than ever."
- Dr. Rice was invited to speak about CPRIT at the Texas Cancer Policy Forum, hosted at the Capitol Extension Auditorium by the American Cancer Society-Cancer Action Network on Oct. 14.
- Wayne Roberts appeared on Capital Tonight as Paul Brown's guest on Sept. 14.
- A story about CPRIT and its product development research program appeared in the Dallas Morning News on Sept. 25.
- An op-ed by Pete Geren, promoting the CPRIT conference, ran in the Austin American-Statesman just prior to the event.
- The Communications team is updating the message platform and developing plans for the upcoming year.

Social Media

The communications team continues to use social media outreach, including Twitter and Facebook, to publicize CPRIT-generated content along with news and information about and from grantees, advocates and other trusted sources.



CPRIT Funds Recruitment of Top Scientists for Texas Academy

Leonor Mateus Ferreira

AUGUST 20TH, 2015 AT 1:28 PM

The Cancer Prevention and Research Institute of Texas (CPRIT) has granted seven awards totaling \$23,000,000, which will be used by different academic facilities to hire top scientists. The grants were awarded through CPRIT's academic research program and are expected to attract seven new cancer specialists to the region, as announced by the institute in a press release. Among the scientists, there are two distinguished senior researchers.

The awarding of the seven grants was determined through CPRIT's research review process, recommended by the Scientific Review Council and ratified by the Oversight Committee (OC). "Over the last six years, CPRIT funding has made it possible to recruit nearly 100 of the top cancer scientists in the world to Texas research institutions," stated CPRIT's CEO Wayne Roberts. "With these latest grants, we're well on our way to assembling the finest cluster of cancer expertise in the country."

Thanks to the academic research program grants, five first-time, tenure-track faculty members were invited to join academic facilities in Texas. \$2,000,000 in funding was awarded for the recruitment of **Dr. Charles Lin**, PhD, from the Dana-Farber Cancer to **Baylor College of Medicine**, while another \$2,000,000 were awarded for the recruitment of **Dr. Leng Hand**, PhD, from the University of Texas MD Anderson Cancer Center to the **University of Texas Southwestern Medical Center**.

Dr. Jan Erzberger, PhD, was recruited from the Eidgenossische Technische Hochschule (ETH) Zurich to the University of Texas Southwestern Medical Center with the support of a \$2,000,000 grant. Also to be added to the faculty at the UT Southwestern Medical Center are **Dr. Kendra Frederick**, PhD, from the Whitehead Institute for Biomedical Research, who received a \$3,000,000 grant, and **Dr. Peter Douglas**, PhD, from the University of California, Berkeley, who was granted a \$2,000,000 award.

In the area of established investigators' recruitment, two \$6,000,000 grants were awarded to support the recruitment of **Dr. Frank McKeon**, MD, PhD, who will leave the Genome Institute of Singapore (GIS) to join the University of Houston, as well as **Dr. Yang-Xin Fu**, MD, PhD, from the University of Chicago, who is expected to join the University of Texas Southwestern Medical Center.

CPRIT's Oversight Committee also elected a new presiding officer, Pete Geren, who will replace William Rice. The term of the former OC presiding officer expired and will be replaced by Geren, who is also the President of the Sid W. Richardson Foundation and served between 2001 and 2009 as Special Assistant to the Secretary of Defense, Acting Secretary of the Air Force, Under Secretary of the Army and Secretary of the Army in the U.S. Department of Defense.

Since Geren will leave the position he occupied as vise presiding officer, Will Montgomery became the new vice presiding officer. Currently a partner at Jackson Walker LLP, Montgomery specializes in commercial litigation and arbitration. The committee also decided to re-elect Amy Mitchell, a cancer survivor and real estate attorney, as the OC's secretary. All three joined CPRIT's OC in 2013.

http://bionews-tx.com/news/2015/08/20/cprit-funds-recruitment-top-scientists-texas-academy



CPRIT gives UT Southwestern \$13M in grants for recruitment

Aug 21, 2015, 6:55am CDT Updated Aug 21, 2015, 7:27am CDT

Lance Murray
Digital Content
Producer
Dallas Business
Journal



The University of Texas Southwestern Medical Center in Dallas has received \$13 million in grants from the Cancer Prevention and Research Institute of Texas.

Austin-based CPRIT announced this week that it has given these grants for recruitment for tenure-track faculty to UT Southwestern:



UT Southwestern Medical Center in Dallas.

LANCE MURRAY

- \$2 million for the recruitment of Jan Erzberger, Ph.D. from ETH Zurich.
- \$3 million for the recruitment of Kendra Frederick, Ph.D. from the Whitehead Institute for Biomedical Research.
- \$2 million for the recruitment of Peter Douglas, Ph.D., from the University of California, Berkeley.

UT Southwestern received \$6 million for the recruitment of established investigator Yang-Xin Fu, M.D., Ph.D. from the University of Chicago.

Earlier this year, UT Southwestern received \$16.6 for other recruitment efforts.

Through May, UT Southwestern was the top recipient of grants from CPRIT, having received a total of \$252,831,420.

To date, CPRIT has awarded \$1.35 billion in grants to Texas researchers, institutions and operations, CPRIT said.

http://www.bizjournals.com/dallas/blog/morning_call/2015/08/cprit-gives-ut-southwestern-13m-in-grants-for.html

Austin American-Statesman

UT gets \$6 million to hire professor

- MARY ANN ROSER, AMERICAN-STATESMAN MONDAY, SEPTEMBER 14, 2015

The University of Texas at Austin will use a \$6 million grant from the Cancer Prevention and Research Institute of Texas, known as CPRIT, to hire Thomas Yankeelov as a professor of biomedical engineering. Yankeelov, who has expertise in computational biology, comes to Austin from Vanderbilt University and is expected to work with the UT Dell Medical School on research.

The grant was among five awards totaling \$17.7 million that CPRIT divvied out to four Texas universities to hire prestigious cancer scientists.



CPRIT and the CAP Foundation offering See, Test & Treat Program

Published 09/14 2015 05:36PM

Updated 09/14 2015 05:36PM



AUSTIN, Texas

The Cancer Prevention and Research Institute of Texas (CPRIT) today announced the release for applications for See, Test & Treat, an innovative breast and cervical cancer screening program of the College of American Pathologists (CAP) and the CAP Foundation.

CPRIT will award up to \$25,000 for each See, Test & Treat program providing same-day screenings, results, education and access to follow-up care for uninsured and underserved women in Texas. Applications must be submitted by January 7, 2016.

"Our collaboration with the CAP Foundation underscores CPRIT's emphasis on targeting populations in Texas where significant disparities in cancer incidence and mortality exist," said Dr. Becky Garcia, the agency's chief prevention and communications officer. "By providing Texas women screenings and opportunities to learn more about their risks, we can detect cancers earlier, when the potential for survival is greatest."

See, Test & Treat is CPRIT's first collaboration with a national organization on a cancer prevention initiative.

The program is targeted to medically at-risk populations faced with financial, linguistic, social, and cultural barriers to health care.

"As physicians who diagnose disease, pathologists understand the value of routine cervical and breast cancer screening. We must help women realize the need for regular cancer screening," said CAP Foundation Board President Jennifer Laudadio, MD, FCAP. "That's why we are thrilled to be collaborating with CPRIT and expanding our reach to serve more women in Texas."

As collaborators, CPRIT will review, select and fund applications for the See, Test & Treat programs offered in Texas while CAP Foundation will provide program guidance and educational materials. Each program brings together pathologists, gynecologists, radiologists, family medicine practitioners, laboratory technicians, nurses, outreach specialists and community advocates for screenings, test results, follow-up care and health education counseling.

Breast cancer is expected to take the lives of nearly 3,000 women in Texas this year and cervical cancer will account for close to 400 deaths, according to the Texas Cancer Registry. The incidence of both breast and cervical cancer among minority women is higher than that of the general population.

"See, Test & Treat allows women to be seen, tested, and referred for follow up care in one visit, removing significant barriers, including financial, language, transportation, or the need to take additional time off work." Dr. Garcia noted.

Since 2010, the program has provided services to women in 12 U.S. cities, including three in Texas—Austin, Houston and Conroe. In Austin, more than 15 percent of the women screened had abnormal mammograms.

"Women 40 and older from underserved Hispanic communities were one of our target populations to serve," said Dr. Jennifer Blankenship, who led See, Test & Treat last year at St. David's Medical Center in Austin. "Hispanic and African-American women in Texas have a higher mortality rate from breast cancer despite having lower disease rates than the general population. That is largely because they tend to participate less in screening programs and are diagnosed at later stages."

For general information on eligibility criteria, the application process, and other details about the CPRIT grant, visit www.cprit.state.tx.us/funding-opportunities/.

About CPRIT

Since 2009, CPRIT has awarded more than \$1.35 billion in grants to Texas researchers, institutions and organizations. CPRIT provides funding through its academic research, prevention and product development research programs. Programs made possible with CPRIT funding have reached all 254 counties of the state, brought nearly 100 distinguished researchers to Texas, advanced scientific and clinical knowledge, and provided nearly 2.5 million life-saving education, training, prevention and early detection services to Texans. Learn more at www.cprit.texas.gov. Follow CPRIT on Twitter @CPRITTexas.gov follow CPRIT on Twitter @CPRITTexas.gov. Follow CPRIT on Twitter @CPRITTexas.gov.

About the College of American Pathologists and CAP Foundation

As the leading organization for board-certified pathologists, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. With more than 18,000 physician members, the CAP has led as the gold standard in laboratory accreditation for 50 years with more than 7,600 CAP-accredited laboratories in 50 countries. Find more information about the CAP at cap.org. Follow CAP on Twitter at @pathologists.

The CAP Foundation, its philanthropic arm, supports patient-centered and humanitarian initiatives led by pathologists, striving to connect people in underserved communities with the specialized skills of pathologists. Contact the CAP Foundation capind@cap.org or follow us on Twitter at #seetesttreat.

CAP Foundation funding for See, Test & Treat is made possible through the continued generous support of CAP member pathologists, staff, foundations, industry, and private donations. Learn more and donate: foundation.cap.org

Copyright Cancer Prevention and Research Institute

Austin American-Statesman

Austin biotech firm Mirna Therapeutics sets terms for \$80 million IPO

By Lori Hawkins

Posted: 1:52 p.m. Friday, Sept. 18, 2015

Austin-based biotech company Mirna Therapeutics on Friday set the terms for an initial public offering of stock that could raise up to \$80 million.

Mirna Therapeutics plans to offer 4.65 million shares of stock at a price range of \$13 to \$15 per share, according to a Friday filing with the U.S. Securities and Exchange Commission. The underwriters for the offering — Citigroup, Leerink Partners, Oppenheimer and Cantor Fitzgerald — will also have options to buy up to 697,500 additional shares, according to securities filings.

If the underwriters purchase those shares, and all shares price at the \$14 midpoint of the proposed range, the IPO could raise about \$80 million. Mirna Therapeutics estimates it will receive net proceeds of about \$68 million from the offering if the underwriters exercise their purchase options.

The company expects the offering to price the week of Sept. 28, according to securities filings.

At the same time as its IPO, Mirna Therapeutics plans to offer a separate private placement stock offering of about 1.2 million shares to the Cancer Prevention and Research Institute of Texas.

The agency — commonly known as CPRIT — was formed by the Legislature to facilitate cancer research in Texas. Mirna Therapeutics received a \$10.3 million grant from CPRIT in 2010. CPRIT also approved a \$16.8 million grant to Mirna Therapeutics in 2014, but those funds have not yet been dispersed to the company, a CPRIT spokesman said Friday.

The private offering to CPRIT could net Mirna Therapeutics \$16.8 million, in addition to the \$68 million it could net from the IPO, according to securities filings.

Mirna Therapeutics plans to trade on the Nasdaq exchange using the trading symbol MIRN.

Mirna Therapeutics is developing treatments for cancer and other diseases using microRNA, molecules that play crucial regulatory roles in cells. The company's MicroRNA Replacement Therapy involves the introduction of synthetic micro RNA into tumors to trigger their death.

The company was spun off in 2007 from Asuragen Inc., which develops molecular diagnostic tests for cancer and other diseases. Both companies were founded by Austin biotech veteran Matt Winkler, who sold his first company, Ambion Inc., for \$273 million to Applied Biosystems in 2006. Winkler remains on Mirna Therapeutics' board of directors, while Paul Lammers became the company's president and CEO in 2009.

In May, Mirna Therapeutics raised \$41.8 million to continue human drug trials of its cancer-fighting treatments.

The company began its first clinical trial on its lead therapeutic product, called MRX34, two years ago. MRX34 is being used to treat patients with heptocellular carcinoma, other solid tumors and hematological malignancies.

Mirna Therapeutics eventually hopes to treat solid cancer types such as primary liver cancer and hermatological cancers such as leukemia and lymphoma.

As of June 30, Mirna Therapeutics had 24 employees and had \$41.6 million in cash and cash equivalents on hand, according to securities filings.

Mirna Therapeutics is the fourth Austin-based company to file for an IPO this year. XBiotech, an emerging developer of cancer-fighting drugs, raised \$76 million in an April IPO. In August, Amplify Snack Brands, which makes health-conscious popcorn and tortilla chips, raised \$235 million.

Meanwhile, Austin-based Aeglea BioTherapeutics, which develops drug therapies to fight cancer, filed in June to raise up to \$86 million but has not yet set a date for its IPO.

The Dallas Morning News

Texas' cancer-research agency survived a scandal. Now, it hopes to prove it's working

By ROBERT T. GARRETT

Published: 25 September 2015 01:55 PM Updated: 27 September 2015 11:18 PM



An \$11 million state cancer-treatment commercialization grant to a Dallas biotechnology firm, Peloton Therapeutics, housed in this building at UT Southwestern, spawned a contracting-deception indictment against Jerald "Jerry" Cobbs.

> AUSTIN - The state's cancer-research agency has survived scandal and tumult, and its leaders and boosters say it's in its prime, flush with money, and the envy of other states.

Nearly halfway through spending the \$3 billion voters gave it eight years ago, though, the Cancer Prevention and Research Institute of Texas is painfully aware that it faces a big sales job. Lawmakers already have begun to debate whether the agency should continue — and if so, what it should do.

Economic development boosters praise the efforts of the agency, known as CPRIT, not just to fund basic research but commercial ventures as well. They say the agency's bets on startup companies and grants helping lure scientists from other states are key to Texas' becoming a "third coast" in biotech.

"Before, we were a bit of a flyover state," said health care investment firm founder Evan Melrose, a physician and businessman who moved from San Francisco to Austin a dozen years ago. "Now, people know we've got great medical resources in this state."

But others, including some in high perches at the Legislature, are less sure the state indefinitely should pay for research and commercial efforts.

Responding to such concerns, CPRIT's staunchest supporters, such as Senate Finance Committee Chairwoman Jane Nelson, say they recognize that for the agency to become a permanent force, it has to deliver.

"There will always be a will to support the eradication of cancer, but at what level and with what funding mechanism?" said Nelson, R-Flower Mound. That "is going to be determined in large part by how CPRIT performs over the next five years."

Promise, then problems

In 2007, both chambers of the Legislature, by better than 2-to-1 majorities, placed the \$3 billion in bonds before voters. Endorsed by cyclist Lance Armstrong before his doping downfall, the constitutional amendment passed, 61 percent to 39 percent.

Heady talk of curing cancer, which claims more than 35,000 Texans' lives each year, quickly turned to problems, though.

Three CPRIT executives resigned amid controversies over tens of millions in grants. One was indicted. In 2013, the Legislature revamped grant award methods, to improve oversight and prevent conflicts of interest.

The agency has added eight additional employees focused on compliance. It hired a new executive team and rebuilt panels of out of state experts, who recommend where to place its money.

Last month, a Travis County jury acquitted the agency's former chief commercialization officer, Jerald "Jerry" Cobbs, of charges that he deceptively executed a contract for an \$11 million grant to Dallas-based Peloton Therapeutics. Prosecutors said Cobbs didn't disclose the grant hadn't undergone a required business or scientific review. He said he did nothing wrong.

"It was not so much anything negative or criminal, it was just officials' trying to get out these grants and unfortunately, they skirted some rules and regulations," said Rep. Jim Keffer. Keffer, an Eastland Republican, helped Nelson pass the 2007 CPRIT legislation.

Wayne Roberts, CPRIT's executive director, said such problems are firmly in the past.

He noted that earlier this month, M.D. Anderson Cancer Center researcher James Allison won the Lasker Award for clinical research, very often, a preliminary to winning a Nobel prize. In 2011, CPRIT ponied up \$10 million to help lure Allison and his team to Houston from Memorial Sloan Kettering in Manhattan.

CPRIT also just delivered its 2.5 millionth prevention service. The screenings have helped 2,000 Texans detect their cancers.

"Morale doesn't need much boosting," said Roberts, who was budget director for former Gov. Rick Perry after 18 years at a key legislative budget agency. "This stuff is boosting us."

But the agency has to spend 10 percent of its money on prevention, by law. And luring "established scholar" rock stars of anti-cancer research is also an easy sell as a success story.

"Everyone acknowledges [CPRIT's] great work in prevention and its role in bringing talent and investment to Texas," Nelson said.

Sen. Charles Schwertner, though, has questioned the need for the state to issue grants for basic research and product development.

Schwertner, a Georgetown Republican who is the Senate's chief health policy writer, said he is skeptical that CPRIT, which annually awards \$300 million, should try to mimic the National Institutes of Health, which dish out billions.

Schwertner also panned CPRIT's push to fund product development. Over six years, it has sunk \$250 million into 27 private biotech companies.

"I'm not sold that money for translation from bench research to commercialization is what the state should be doing," he said. "Private industry is very effective at finding a way forward if they see a dollar amount at the end," he said, referring to drugs and devices that hold promise.

Roberts, the CPRIT chief, said the 2007 legislation made it a top priority for the agency to help get affordable cancer therapies to market and attract high-paying biotech jobs. He has spoken of a "valley of death" in funding that crushes most potential cancer therapies, just when they are first undergoing safety and effectiveness tests.

Dennis McWilliams, president and co-founder of Austin-based Apollo Endosurgery Inc., credits a 2010 CPRIT grant of \$5 million with sparing his company's stomach cancer devices from an early demise during testing.

"The economy collapsed and venture capitalists weren't investing," he recalled. "If it weren't for CPRIT, we may not have survived that period."

Apollo has attracted \$100 million in investment and has about 100 Texas employees, he said

Matt Winkler, who has founded three biotech companies in Austin, said it takes a varied community to generate success: scientists, experienced startup managers, savvy investors and mentors who can dispense advice.

Texas has had scientists at its universities, but their technologies often are commercialized on the East Coast and West Coast, Winkler said.

"What's needed is more money to help move technology out of universities and into companies here in Texas," he said.

Biotech venture capitalist Matt Crawford of Austin said luring managerial talent from Boston or California to Texas is difficult because there just aren't enough fallback opportunities.

"Texas is a good market to recruit to right now. There's a great perception right now of the state," he said. "But the toe stubber for all these guys and gals is when they ask themselves, 'Do I really, really want to move there? Move my family? If it doesn't work out, what comes next?"

Easing resentments

For now, CPRIT has several years to win over skeptics who may help decide its future. Its lease on life lasts until 2021. That's when lawmakers will have to decide whether to find new state dollars for the effort or pack CPRIT off into a diminished future, living solely off royalties from product development grants. So far, that revenue is barely a trickle.

To survive politically, CPRIT probably has to ease some parochial resentments, some university and industry officials said. A *Dallas Morning News* analysis of data from NIH and the state suggests it's well on its way.

At Cobbs' trial, prosecutors and witnesses recounted bitter protests by Houston interests after committees overseen by Nobel laureate Al Gilman, who was CPRIT's chief science officer at the time, awarded science grants to his former colleagues at UT Southwestern Medical Center in Dallas.

Through 2012, UT Southwestern received about 36 percent more in CPRIT grant money than M.D. Anderson, also a UT entity.

That was in spite of the fact that last year, M.D. Anderson had active grants from the National Cancer Institute worth almost \$180 million, nearly three times what UT Southwestern had (\$47 million), The Morning News found.

Over CPRIT's entire six years of operation, though, UT Southwestern's lead has narrowed. While CPRIT has awarded the most money — \$264 million — to UT Southwestern, that's only 14 percent more than M.D. Anderson's \$231.5 million.

Houston's Baylor College of Medicine is the third-biggest recipient of CPRIT grants, with \$171.5 million.

Beyond those academic "super centers," the Houston area has a much deeper bench. It's home to nine other entities that each have received between \$12 million and \$48 million. In North Texas, aside from UT Southwestern, no other institution, public or private, has exceeded Peloton's \$11 million.

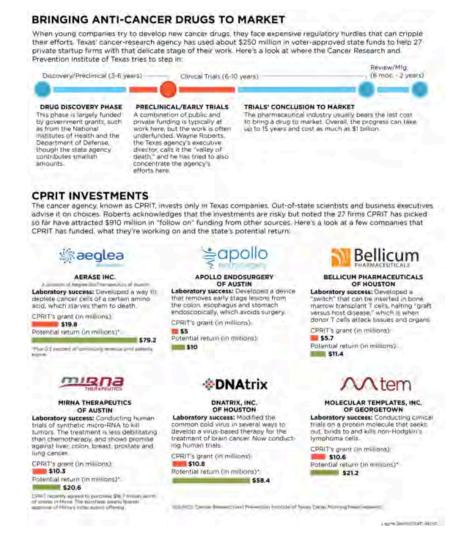
Schwertner, the Senate skeptic, said that early in the next decade, CPRIT may have to be self-sufficient.

In this year's legislative session, he authored an unsuccessful bill that would have required the agency to begin planning for a life that possibly would include no further state funds — just royalties and payments from companies it's backed.

Having no state support could be fatal. So far, CPRIT has received \$2.2 million in royalties. That wouldn't pay for more than about six months of salaries for its current 32-person staff.

Roberts said he's not worrying about what a future Legislature might decide.

"We still have more than \$1.5 billion of that \$3 billion to award, plus six years," he said. "There's an awful lot of good left for us to do."



http://www.dallasnews.com/news/state/headlines/20150925-texas-cancer-research-agency-survived-a-scandal---now-it-hopes-to-prove-it-s-working.ece



UTHealth Receives \$5.7 Million in CPRIT Funding

Anna Tan, RN OCTOBER 2ND, 2015 AT 7:00 AM



A pair of young and promising scientists with fresh ideas for oncological research have recently been recruited by the University of Texas Health Science Center at Houston (UTHealth). Wa Xian, Ph.D., a stem cell researcher, and Leng Han, Ph.D., a computational biologist, were awarded \$3.7 million and \$2 million, respectively, from the Cancer Prevention & Research Institute of Texas (CPRIT) to help further their investigations.

"The CPRIT program has been tremendously important to help us recruit some of the most outstanding young scientists in cancer research who will help us to continue to build excellence in this and related research areas in the future," said George Stancel, Ph.D., executive vice president for academic and research affairs and holder of the Roger J. Bulger, M.D., Distinguished Professorship at UTHealth. "These are the type of young investigators who will develop into our future institutional leaders in this area and the CPRIT support is critically important to help us recruit them to UTHealth."

Dr. Xian will be focusing his work on ovarian cancer while Dr. Han's will work around the genetic aberrations that drive uninhibited cell proliferation, such as in cancer.

"Dr. Xian brings a cutting-edge approach to tissue-specific stem cells that can be used to develop cell therapies and further the understanding of disease," said Brian R. Davis, Ph.D., director of the Center for Stem Cell & Regenerative Medicine at the Brown Foundation Institute of Molecular Medicine for the Prevention of Human Diseases at UTHealth.

Dr. Xian is aware that despite the many advances in ovarian cancer treatment, a small population of cells may be treatment-resistant and could lead to cancer relapse. "In my lab, we are generating patient-specific libraries of cancer stem cells to identify and target a particularly nasty subset that survives chemotherapy and comes back as a repeat disease," said Dr. Xian, an assistant professor at UTHealth Medical School.

Dr. Han will be exploring the molecular channels between 20 distinct types of cancer, including cancer of the pancreas and breast. Specifically, Han will be attempting to identify RNA that helps differentiate cancer cells from normal cells. "We already have huge volumes of data on DNA and RNA sequences from cancer patients," said Dr. Han, assistant professor of Biochemistry and Molecular Biology. "The challenge is to interpret this vast amount of sequence information and I'm developing computational pipelines to address this challenge. When we get a better understanding of the molecular mechanisms of cancer, we can develop better diagnostic and therapeutic strategies."

"Dr. Han's extensive experience with next generation sequence data from large cancer data resources has prepared him for this research," concluded Rod Kellems, Ph.D., chairman of the Department of Biochemistry and Molecular Biology at UTHealth.

http://bionews-tx.com/news/2015/10/02/uthealth-receives-cprit-funding-worth-5-7-million-for-two-scientists-in-cancer-research/



Grant funds preventive care services for breast cancer

BY: Michelle Gaitan POSTED: 9:25 PM, Oct 3, 2015 UPDATED: 10:45 PM, Oct 3, 2015



SAN ANGELO, Texas - The Laura W. Bush Institute for Women's Health has been awarded a nearly \$1.5 million grant that will help it continue to fight cancer.

The institute, on the Angelo State University campus, received the Access to Breast Care for West Texas grant through the Cancer Prevention and Research Institute of Texas in July.

CPRIT grants for preventive care include tobacco cessation programs, vaccinations, screenings for breast, cervical and colorectal cancers, genetic testing, counseling and survivor care.

The grant covers three years of access to cancer prevention services for women in 21 counties in West Central Texas, said Shayla Grelle, program and clinical manager at the Center for Community Wellness, Engagement and Development at ASU.

The WED Center hosts several multidisciplinary initiatives from other agencies, including the ASU Consultation and Research Institute, Community Development Initiatives and the Laura W. Bush Institute for Women's Health, to facilitate the development of new programs, initiatives and processes that serve unmet community needs.

This is an expansion grant that will help the institute cover 21 counties instead of the 14 counties its original grant allowed to provide breast cancer care services for the past four years. The original grant ended this year, Grelle said.

Grelle said the second CPRIT grant will continue to fund the project's breast cancer screening services but also includes cervical cancer detection for the uninsured and underinsured.

The CPRIT funding also will cover transportation costs for women to obtain these services and will support a public awareness campaign targeting women throughout West Central Texas.

"Grant funding will help a tremendous number of women receive breast cancer care," said Linda Ross, regional director for the Bush Institute at ASU. With the last grant 23 women were diagnosed with breast cancer, she said. Since 2012 the institute has provided breast cancer prevention services to more than 1,000 women in West Texas.

"The goal is to provide education with these women, knowing the importance of breast cancer care to catch it in earlier stages," she said. "We've had good responses to our services, and we're the only place in San Angelo that has a program like this to provide the services to uninsured and underinsured women."

For more information about services provided by the WED Center and the Bush Institute at ASU, call 325-942-2754 or visit angelo.edu/services/communitywed.



CPRIT to bring product innovators to Austin conference

Staff report Oct 16, 2015, 5:00am CDT



Wayne Roberts, CEO, CPRIT

ABJ chatted with CPRIT CEO Wayne Roberts recently about the event, which will shed light on how CPRIT has seeded 26 companies that have since gone on to secure about \$930 million in follow-up funding.

How many attendees could be former CPRIT grant recipients, and how does the agency stay involved with recipients to help maximize the impact of the grants? At least half of the registrants are current grantees from CPRIT's academic research, prevention and product development research programs. The conference provides a unique opportunity to interact with grant recipients, and for our grantees to network and compare research and award results with each other. We know from past experience that the resulting collaboration can ignite new ideas, broaden perspectives and connect lines of thinking to address the complexities associated with a disease affecting thousands of Texans and their families every year.

There are also more formal ways that CPRIT stays involved with grantees. The agency requires annual and, in the case of prevention grants, quarterly reports on the grantees' progress. In addition, the CPRIT program officers and managers visit grantees and communicate as needed to seek clarification or answer questions. CPRIT grants specialists also conduct desk audits and site visits.

Based on what you're hearing from researchers and entrepreneurs, what are three topics that are getting a lot of attention in cancer fields? No. 1 is immunotherapy, and we're pleased that our confirmed speakers include CPRIT grantee Dr. Jim Allison from The University of Texas MD Anderson Cancer Center in Houston. His pioneering work in immunotherapy, turning the body's immune system against cancer, won him the prestigious Lasker-DeBakey Clinical Medical Research Award this year. These awards often presage future recognition by the Nobel committee. No. 2 is the recruitment of the best cancer researchers; A recent story in the Chronicle of Higher Education noted how New York and other states are envious of CPRIT's resources and its success in helping to recruit almost 100 preeminent cancer researchers to Texas institutions. And No. 3 is hepatocellular cancer, or HCC. Texas has the second-highest death rate from HCC in the nation and most patients are diagnosed at late stages. Effective prevention and early detection measures are needed.

How much money is left from the CPRIT bond money to be dispersed as grants? Early next year, CPRIT will reach the halfway point in its funding authorization with around \$1.5 billion remaining for academic research, prevention and product development awards.

Austin American-Statesman

OTHERS SAY PETE GEREN

SATURDAY, NOVEMBER 7, 2015

Special Contributor

CPRIT key in making state leader in cancer research

Geren says

CPRIT has

brought

leading

scientists

to Texas.

This week, the Cancer Prevention and Research Institute of Texas (CPRIT) will hold its Innovations in Cancer Prevention and Research Conference in Austin.

The event is an opportunity for nearly 700 of the finest minds engaged in the fight against cancer to connect, collaborate and consider new and promising opportunities for discovering treatments for cancer.

Cancer manifests itself in hundreds of ways in humans and poses what is perhaps the most vexing challenge facing medical researchers today. This is the reason author Siddhartha Mukherjee called cancer "The Emperor of All Maladies" in his Pulitzer Prize-winning book.

As discouraging as this may seem, the fact is effective treatments for many cancers - even cures - are being discovered today. For example, earlier this year, a research scientist born and raised in South Texas, Dr. Jim Allison, was awarded the prestigious Lasker-DeBakey Clinical Medical Research Award for what may be one of the most important breakthroughs in cancer history - a discovery that frees the immune system to attack tumors. Several years ago, CPRIT saw promise in Dr. Allison's research, approved a grant to bring him and his team to the University of Texas MD Anderson Cancer Center in Houston, and continues to support his work.

Also at MD Anderson is Dr. Raghu Kalluri, another CPRIT success story. Just months ago, Dr. Kalluri and his team announced they had discovered a protein that pancreatic tumors consistently shed into the blood. It is a significant discovery that



Despite the challenges of cancer, many treatments — even cures — are being found today.

may lead to early detection of pancreatic cancer through a simple blood test.

Allison and Kalluri are among the nearly 100 top-level researchers and labs CPRIT has brought to Texas. CPRIT funding also has put more than 1,000 college- and graduate-level students into those labs to train a new generation of researchers for the fight against cancer. Dr. Bill Rice, a CPRIT board member, calculates that the Institute's investments have added more than 2,000 research years to Texas institutions including Texas A&M University, the University of Texas at Austin, UT Southwestern, Baylor College of Medicine, UT Health Science Center at San Antonio, Rice University, UT Health Science Center at Houston, Texas Tech University and UT Medical Branch at Galveston.

Additionally, CPRIT grants are invigorating the life sciences industry in Texas. More than 4,700 direct jobs have been created in Texas as a result of CPRIT. These include doctors, scientists, life science entrepreneurs, nurs-

es, lab technicians, diagnosticians, health care educators and navigators, data managers and support professionals. What's more, \$250 million in CPRIT product development research awards have catalyzed at least \$910 million in private sector follow-on investment.

We all know early detection and prevention save lives, but here's another encouraging fact: For every CPRIT dollar spent for screening and prevention, Texas receives \$7.16 in economic benefits, including treatment cost savings and productivity maintenance. CPRIT's prevention projects have provided more than 2.5 million educational and clinical services. The 1.3 million clinical preventive services have included 578,725 screenings that have identified 47,523 abnormal results, over 3,732 cancer precursors and nearly 2,000 cancers.

Because of the continued support of the Texas Legislature and Texas taxpayers, we can rightly claim that we have momentum in the fight against cancer. Today, Texas is on the frontier of cancer science.

CPRIT still has \$1.5 billion to award over the next six years. Investing that money in the most promising cancer prevention, treatment and cures is the institute's full-time focus. It is a mission that is bringing us closer to the day when the "Emperor of All Maladies" ceases to be a life-threatening disease.

Geren is the president of the Sid W. Richardson Foundation, which provides grants to educational, health, human service and cultural nonprofit organizations in Texas. He is presiding officer of CPRIT's oversight committee.

Oversight Committee Meetings and Standing Subcommittee Meetings FY 2016

November 2015

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3 PIC Meeting CPRIT Staff Only	4 Portal Opens	5 Board Governance	6 Diversity	7
8	9 Audit	10 Prevention	11 Sci Research	12 Prod Dev	13 Nominations	14
15	16	17	18	19 Oversight Committee Meeting	20	21
					Febr	uary 2016
Sunday	Monday	Tuesday	Wednesday	Thursday	Febr Friday	ruary 2016 Saturday
Sunday 1/31	Monday 1	Tuesday 2 PIC Meeting CPRIT Staff Only	Wednesday 3 Portal Opens	Thursday 4 Board Governance		
-	-	2 PIC Meeting		4 Board	Friday	Saturday

						May 2016
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3 PIC Meeting CPRIT Staff Only	4 Portal Opens	5 Board Governance	6 Diversity	7
8	9 Audit	10 Prevention	11 Sci Research	12 Prod Dev	13 Nominations	14
15	16	17	18 Oversight Committee Meeting	19	20	21

					Au	gust 2016
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
7/31	1	2 PIC Meeting CPRIT Staff Only	3 Portal Opens	4 Board Governance	5 Diversity	6
7	8 Audit	9 Prevention	10 Sci Research	11 Prod Dev	12 Nominations	13
14	15	16	17 Oversight Committee Meeting	18	19	20

Note: Unless the subcommittee members agree to a different time, all subcommittee meetings will begin at 10:00 a.m. with the exception of Diversity and Nominations that will begin at 10:30 a.m. Members of the Audit and Program subcommittees should allocate 1.5 hours for a meeting. All others subcommittee meetings require one hour.